PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUGS*KUKKIL CHOORANAM* (INTERNAL) AND *THUVARA ENNAI* (EXTERNAL) IN THE TREATMENT OF *PUN*(*NAALAVIBATHA PUN* -VARICOSE ULCER)

The dissertation Submitted by

Dr. C. Sasikala,

P.G.Scholar

Under the Guidance of

Dr.V.MahalakshmiM.D(s),

Lecturer,

Department of SirappuMaruthuvam.

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DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled “Preclinical and Clinical Study of Siddha drugsKukkilChooranam (Internal) and ThuvaraEnnai (External) in the Treatment of Pun (Naalavibatha Pun-Varicose Ulcer)is a bonafide and genuine research work carried out by me under the guidance of**Dr.V.Mahalakshmi,M.D(s),** Lecturer**,** Department of **SirappuMaruthuvam**, National Institute of Siddha, Chennai -47, and the dissertation has not formed the basis for the award of any Degree, Diploma, Fellowship or other similar title.

Date: **Signature of the Candidate**

Place: Chennai-47 **Dr.C.Sasikala**

BONAFIDE CERTIFICATE

Certified that I have gone through the dissertation submitted by **Dr.C.Sasikala, (Reg.No: 321413207)** a student of final year M.D(s), Branch-III, Department of **SirappuMaruthuvam**, **National Institute of Siddha**, Tambaram Sanatorium, Chennai-47, and the dissertation work has been carried out by the individual only. This dissertation does not represent or reproduce the dissertation submitted and approved earlier.

Place: Chennai-47

Date:

Name and Signature of the Guide,
Lecturer,
Department of SirappuMaruthuvam,
National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

Name and Signature of the HOD,
Department of SirappuMaruthuvam,
National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

Forwarded by the Head of the Institution
National Institute of Siddha,
Tambaram Sanatorium,
Chennai-47.

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INTRODUCTION

INTRODUCTION

The origin of Siddha system is shrouded in mythology, tradition and religion of ancient manuscripts. The main aim of Siddhars denoting that the carrier of the soul for the attainment of happiness and to attain heavenly bliss. They found diseases as one of the obstacles to reach God. So they bestowed to the world the siddha medicine to cure diseases.

Word Siddha comes from the word Siddhi, which means an attainment of perfection or heavenly bliss. Siddhi generally refers to Attama siddhi i.e., the eightgreat supernatural powers. Those who attained or achieved the above said powers are known as Siddhars. Siddhars laid foundation for this system of medicine.

The diagnosis of disease in siddha system of medicine relies on the eight ways of examination methods *(Envagai thervu)* as *Naadi, Sparisam, Naa, Niram, Mozhi, Vizhi, Malam* and *Moothiram* which are evaluated in terms of the three humours. According to Siddha system of medicine five elements (Earth,Water, Fire, Air, and Space) of nature combination with each other and form the basis of three humours of the body namely ***Vaatham, Pitham and Kabam.*** Whenever there is derangement in these three humours the resultant would be the Disease.

"Pun" is defined as discontinuity of skin tissue in any part of the body. According to *Siddhar aruvai maruthuvamPun* is classified into 2 types (*Dhutta viranam, Adhutta viranam*). *Naalavibatha pun* is comes under *dhutta viranam*. Siddha system explains the *naalavibatha pun* formed due to abnormalities happened in the naalangal (veins) due to life style changes, climate and food habits.

Naalavibatha pun may be correlated with varicose ulcer in modern science. The varicose ulcer (VU) is one of the most severe manifestations of chronic venous insufficiency (CVI) of the lower limbs, a disease of great importance to public health due to its high incidence, prevalence and the high socioeconomic impact that it brings, since it is difficult to treat and requires prolonged work absenteeism. This morbidity frequently presents associated with varices and trophic lesions of the lower limbs. Chronic venous insufficiency may be classified as a syndrome that includes from telangiectasia to active ulcers, originating in chronic venous hypertension caused by venous obstruction or reflux, with or without muscle pump insufficiency.

The extrapolated prevalence rate of varicose vein in India providing warning is about 47,928,177 in statistics. According to another estimate 15 to 20% of population in India is suffering vein disease.

Despite being more common in elderly persons, with a peak of prevalence in individuals aged between 60 and 80 years, 22% of those affected are approximately 40 years of age, while 13% develop VU before they reach 30 years of age, evidencing the losses that this disease causes in work production. Of all lower limb ulcers, approximately 70 to 80% are caused by CVI.

There are multiple forms proposed for the treatment of VU, from simple elevation of the affected limb to surgery, including grafts and various types of dressings. Elevation of the limb is simple and accelerates healing of the ulcer, but cannot be performed isolated nor continually in patients who are not bedridden. Skin grafts have strict indications and can only be performed in specialized centres, in which surgery of the superficial system is less costly and easier to carry out, with a good cure rate and decreased recurrence rate, but it is only indicated in patients with a predominance of superficial venous system insufficiency.

In Siddha system of medicine, drugs are prepared with ingredients of herbs, minerals, metals and animal origins. Siddhars used single or combination of drugs for their medicinal preparation. In addition to herbs little amount of *Muppu*(Universal solvent or Quit essence salt) is added to increase its potency, efficacy, therapeutic index because of the long shelf life. Exclusivities of Siddha system are *Kayakarpam, Attangayogam, Muppu, Varmam, Envagai thervu, manikkadai nool, Sarakkuvaippu*. Siddhars classify the siddha medicines into 32 types of internal medicine and 32 types of external medicine.

Kukkil chooranam and *Thuvara ennai* are one among them. Ingredients of *Kukkil chooranam (Shorea robusta, Smilax china, Piper nigrum, Piper longum, Hyocyamus niger, Myristica fragrans, Terminalia bellirica, Phyllanthus emblica)* and *Thuvara ennai (Gingely oil, Terminalia chebula* and*Areca catechu)* are having wound healing activity**.**Hence I have selected these drugs for my dissertation.

AIM AND OBJECTIVES

AIM:

The purpose of this trial is to evaluate the therapeutic efficacy of siddha herbo-mineral drugs "*Kukkil chooranam*"(Internal) and "*Thuvara ennai*" (External) in the treatment of *Pun* (*Naalavibatha pun*- Varicose ulcer)

OBJECTIVE:

PRIMARY OBJECTIVE:

- To evaluate the therapeutic efficacy of siddha drugs "*Kukkil chooranam"*(Internal) and "*Thuvara Ennai*" (External) in reducing pain, itching, oozing and healing of Varicose ulcers (*Naalavibatha pun*)

SECONDARY OBJECTIVE:

- To study the Siddha basic principles towards the efficacy of medicine.
- To evaluate the safety of the trial drugs by doing toxicological studies short term and long term studies in animal models.
- Biochemical analysis of drug**.**

REVIEW OF LITERATURE

SIDDHA ASPECT

LITERATURE REVIEW SIDDHA ASPECT

Synonym:*Naala suruttu pun, Narambu suruttu pun*.

Definition (*Iyal*):

"*Naalam*" or vein is a vessel which carries the blood from a system of minute tubes termed capillaries to the heart.

"*Naala thaabam*" is difined as inflammation of vein.

"*Pun*" is defined as discontinuity or break in a bodily membrane that impedes the organ of which that membrane is a part from continuing its normal function.

Aetiology:

"பயில் மொழியீர் திரேகத்தில் கிருமிதானே
பரந்துதிரி குட்டம்போல் புள்ளி காணும்
மயலதுவும் கிருமியுந்தான் நடந்து புக்கில்
மேனியது சரசரெனவெடித்து புண்ணாம் – குருநாடி

According to text *Siddhar Aruvai maruthuvam* causes of ulcer are,

- Derangement of three humours
- Abscess
- Any Trauma
- Burns
- Insect bite

According to text *Agasthiyar Rana vaithiyam* causes of ulcer are,

- Derangement of three humours
- Trauma

According to *T.V.Sambavasivam pillai* Dictionary causes of ulcer are,

- Idiopathic
- Traumatic

Classification:

According to text *Siddhar Aruvai maruthuvam*,

- *Dhushta viranam*-15
- *Adhushta viranam*-45

Other classification,

- Derangement of three humours
  - *Vali pun*
  - *Azhar pun*
  - *Iyya pun*
  - *Vali pitha pun*
  - *Vali iyya pun*
  - *Pitha iyya pun*
  - *Mukkutra pun*
  - *Kuruthi pun*
  - *Kuruthi thee pun*
  - *kuruthi vali pun*
  - *kuruthi iyya pun*
  - *kuruthi vali iyya pun*
  - *Kuruthi vali pitha pun*
  - *Kuruthi pitha iyya pun*
  - *Kuruthi mukkutra pun*
  - *Velutha kuruthi pun*
- Wound caused by trauma

According to text *Agasthiyar Rana vaithiyam*,

- *Dhushta viranam*-4
- *Adhushta viranam*

According to text *Anubava vaidhya deva ragasiyam*

- *Nisa viranam(Dhushta viranam*)-15
- *Aaganthuga viranam(Adhushta viranam*)-49

Others

- *Sutha ratha viranam*
- *Sathiyo viranam* – 8

According to text *viranakarappan roga sigitchai*,

- *Nija viranam*
- *Aaganthuga viranam*

Other,

- *Sutha viranam* (Simple ulcer)
- *Dhushta viranam* (Chronic ulcer)

According to *T.V.Sambavasivam pillai* Dictionary various type of ulcer given below,

- *Neruppu pun*(Burns)
- *Mega pun*(Venereal ulcer)
- *Vellai pun*(Gonorrheal ulcer)
- *Aaraa pun*(Chronic ulcer)
- *Kiranthi pun*(Syphilitic secondary rashes)
- *Ottu pun*(Contagious sore)
- *Kuzhi pun*(Deep sore or perforating ulcer)
- *Raasa pun*(Diabetic carbuncle)
- *Karappan pun*(Eczema)
- *Parangi pun*(Syphilitic primary sore)
- *Vettu pun*(Incised wound)
- *Kaaya pun*(Traumatic sore)
- *Azhi pun*(Sloughing sore)
- *Korukku pun*(Chancre)
- *Veditha pun*(Fissurel ulcer)
- *Azhar pun*(Inflammed ulcer)
- *Rasavekkadu pun*(Ulcer caused by mercurial poisoning)
- *Putru pun*(Fungus ulcer)
- *Vayitru pun*(Gastric ulcer)
- *Thulai pun, Purai pun*(Sinus)
- *Ari pun*(Rodent ulcer eating away the tissues)

According to text siddha system of disease ulcer classified into

- *Saruma pun* (Dermatitis)
- *Adhirvu pun* (Dermatitis traumatica)
- *Thee pun* (Dermatitis calorica)
- *Kulirchi pun* (Chill blains or Frost bite)
- *Azhugu pun* (Dermatitis gangrenosa)

- *Nanju pun* (Dermatitis medicamentosa)
- *Veppu noi pun* (Exanthema)
- *Thinavu pun* (Pruritis and Urtecaria)
- *Kirandhi* (Venereal ulcer)
- *Korukku pun* (Chancroid)

Symptoms of ulcer:

According to text *Siddhar Aruvai maruthuvam,*

Due to derangement of three humours classifications of ulcers are

- ***Vali pun ilakkanam:***

  Ulcer is black, red or white in colour; discharge is purulent, pricking pain over the ulcer.

- ***Azhal pun ilakkanam:***

  Onset is acute, Ulcer may be yellow, red, dark red or pale red in colour. discharge is clear. Pain, burning sensation and redness present.

- ***Iyya pun ilakkanam:***

  Itching and pricking pain present, ulcer pale in colour. Discharge sticky in nature.

- ***Vali pitha pun ilakkanam:***

  Pricking pain, redness, dryness, clear and scanty discharge with foul smelling

- ***Vali Iyya pun ilakkanam*:**

  Rough, heavy and hard, itching, pricking pain, the discharge is scanty and sticky in nature

- ***Pitha Iyya pun ilakkanam:***

  Hot, itching, burning sensation, pain, pale in colour, discharge sticky in nature.

- ***Mukkutra pun ilakkanam:***

  Mixture of vatha, pitha and kaba ulcer features.

- ***Kuruthi pun ilakkanam:***

  Red in colour, coral like, very painful, bloody discharge. Symptoms of these ulcers similar to dhushta viranam.

- ***Kuruthi vali pun ilakkanam:***

  Rough, severe pricking pain is found. Discharge is blood stained. Ulcer is red in colour.

- ***Kuruthi pitha pun ilakkanam:***

  Ulcer is red and yellow in colour. Discharge is clear and blood stained.

- ***Kuruthi iyya pun ilakkanam:***

  Ulcer is red in colour, swelling, itching present. Bloody discharge present.

- ***Kuruthi vali pitha pun ilakkanam:***

  Mixture of of features of both *kuruthi vali pun* and *kuruthi pitha pun*

- ***Kuruthi vali iyya pun ilakkanam:***

  Mixture of features of both *kuruthi vali pun* and *kuruthi iyya pun*

- ***Kuruthi pitha iyya pun ilakkanam:***

  Mixture of features of both *kuruthi pitha pun* and *kuruthi iyya pun*

- ***Kuruthi mukkutra pun ilakkanam:***

  Mixture of features of both *kuruthi vali pun,kuruthi pitha pun* and *kuruthi iyya pun*

- ***Velutha kuruthi pun ilakkanam:***

  Ulcer is pale red in colour, centrally elevated, shining without any discharge.

According to *Agasthiyar Rana Vaidhyam,*

Dhushta viranam is classified into 4 subtypes,

- ***Dhushta vaatha viranam:*** Ulcer black and white in colour, ulcer may be deep seated and penetrating the bone, purulent discharge present in ulcer, pricking pain present around the ulcer.
- ***Dhushta pitha viranam:***Ulcer is reddish white or yellow in colour, sudden onset, clear discharge present in ulcer, burning sensation and pain present around the ulcer,
- ***Dhushta silethuma viranam:***Ulcer raised, itching present, discharge sticky in nature, pricking pain present.
- ***Rathavaatha dhushta viranam:***Ulcer bright red or coral like colour, blood stained discharge present in ulcer.

1. Adhushta viranam:

Ulcer present with pus, blood discharge and purulent discharge. But this is easily curable.

2. Sutha ratha viranam:

Centraly elevated papular lesion that is reddish black in colour.

Symptoms of ulcer based on three humours:

Ulcer along with pricking pain, burning sensation, swelling and vomiting are caused by derangement of *vaatham, pitham, kabam* and *ratham* respectively.

According to text *Anubava Vaidhya Deva Ragasiyam,*

Sathiyo viranam:

i. ***Krishta viranam:*** Trauma due to thorn, log, horn. It is a non-healing ulcer present with bleeding.
ii. ***Avakartha viranam:*** It is a perforating and deep seated ulcer.
iii. ***Vichinna viranam:*** Ulcer like cut wound
iv. ***Piravilambi viranam:*** Ulcer look like cut wound, ulcer may be deep seated and penetrating the bone.
v. ***Nibaathika viranam:*** In this type bone exposed in centre of the ulcer which is surrounded by necrotised tissue.
vi. ***Vitha viranam:*** Traumatic ulcer caused by stones.
vii. ***Pinna viranam:*** Ulcer caused by sword, knife like sharp instruments.
viii. ***Vithalitha viranam:*** This is due to apply pressure over a bleeding ulcer and trauma. This may leads to arthralgia and development of ulcer.

According to text *Viranakarappan Roga Sigitchai:*

Nija viranam:

This ulcer spontaneously occurs due to derangement of humours.

Aaganthuga viranam:

This ulcer due to violent truma.

Dhustha viranam:

- Ulcer may be open or closed
- Extensive softness or hardness present

- Base of the ulcer is raised or deep seated
- Surrounding skin may be very cold or hot and pigmented
- Purulent discharge present
- Intolerable pain, swelling and itching were present.

Sutha viranam:

- Ulcer may be in pale colour and soft
- There is no evidence of hyperpigmentation, pain, pus discharge and warmth.

Common sites for the formation of ulcer according to text *Agasthiyar Rana Vaidhyam,*

- *Thol*(Skin)
- *Iraichi*(Muscle)
- *Perunarambu*(Arteries and veins)
- *Sirunarambu*(Capillaries)
- *Keel*(Joint)
- *Elumbu*(Bone)
- *Vayiru*(Abdomen)
- *Marmasthanam*(Genital organs)

Common sites for the formation of ulcer according to *Viranakarappan Sigitchai*,

- *Thol* (Skin)
- *Virai* (Blood vessels)
- *Maamisam* (Muscle)
- *Thasai* naar (Tendon)
- *Sandhigal* (Joints)
- *Elumbu* (Bone)
- *Kudalgal* (GIT)
- *Marmasthaanangal* (*Sirasu*- Head, *Irudhayam*- Heart, *Siruneer* pai- Urinary bladder)

Curable and incurable conditions:

According to text *Agasthiyar2000* (III part)

"புண்ணும்வெளுத்து நீர்மிகுந்து போதக்குத்துவலி மிகுந்தால்
உண்மைப்படவே செங்கலங்கள் கொள்ளாதிருக்கி லூன்செய்யும்
தீண்மைப்படவே செங்கலங்கள் யிரத்தமாகிற் தீராது
நன்னிக்கீழாய்ச் சீழ்விழுந்து பின்னைநனைக்குஞ் செம்புண்ணே
-அகத்தியர் 2000(மூன்றாம் பாகம்)

- Ulcer with pale coloured margin, oozing, pricking pain and formation of granulation tissue is easily curable.
- Ulcer with pus discharge and no formation of granulation tissue are non-healing ulcers.

According to text *Agasthiyar Rana Vaithiyam*

Saathiya ranam:

Healthy adults easily recovered from this condition

Kashta saathiya ranam:

Ulcer in thighs, genitalia, anus, lips, buccal cavity, jaw, eyes, teeth, tongue, blood vessels, ear, abdomen, axilla and breast are difficult to treat.

According to text *Siddhar Aruvai Maruthuvam*

Curable and incurable conditions:

- Age of affected person
- If the shape of the ulcer is oval, triangle and rectangle are easily curable
- Ulcer in eye, nostrils, gums, chest, nipple and joint are difficult to treat.
- Ulcer in diabetes, TB, leprosy and syphilitic ulcer are called non healing ulcer
- Improper medication may delay the healing process
- Ulcer with pus discharge, raised floor, fissures and deep wound are not curable
- Ulcer in Vertex, fingertip, vital points (varmam), deep seated wound which penetrate the bone and bone marrow are not curable.

According to text *Viranakarappan Sigitchai,*

Easily curable wound are,

- Ulcer in healthy adults
- When shape of the ulcer is circular or oval
- When edges of the ulcer is clean
- Ulcer in male genitalia, lips, buccal cavity and cheeks

According to text *Viranakarappan Sigitchai*causes of delayed wound healing,

- Inflammation of tendon with pus discharge
- Surgical removal of blood vessels
- Deep seated ulcers
- Secondary infection in ulcer
- Fracture of bones
- Improper removal of foreign particles
- Toxic bite induced ulcer
- Improper medication
- Irritation of wound by any other object
- Stress
- Alcoholism
- Abnormal sleeping pattern

SIDDHA PATHOLOGY

According to Siddha system of medicine five elements (Earth,Water, Fire, Air, and Space) of nature combined with each other and form the basis of three humours of the body, namely ***Vali (Vatham), Azhal (Pitham) and Iyam (Kapham).*** Whenever there is derangement in these three humours the resultant would be the Disease. *Vaatham* is responsible for all physiological and biological activities of the body. Derangement of *vaatham* leads to stagnation of blood in the affected part of the body. The blood vessels which contain stagnated blood get dilated, coiled and become more prominent. After that inflammatory process occurs at the site due to derangement of *pitham*. The deranged *vaatham* and *pitham* simultaneously leads to derangement of *kabham* which is responsible for the formation of ulcer in the affected part of the body.

***PINIYARI MURAIMAI*(DIAGNOSTIC METHODS):**

Piniyarimuraimai is the method of diagnosing disease. It is based on the following principles:

- *Poriyal aridhal*
- *Pulanal aridhal*
- *Vinaathal*

Poriyal aridhal and *Pulanal aridhal* means examining the patient's **'***Pori'* and '*Pulan'* with that of physician's '*Pori'* and '*Pulan'*.

Imporigal

- *Mei* (Skin)
- *Vai* (Tonge)
- *Kan* (Eyes)
- *Mooku* (Nose)
- *Sevi* (Ear)

***Impulan*:**

- *Osai* (Sound)
- *Ooru* (Sensation)
- *Oli* (Vision)
- *Suvai* (Taste)
- *Naatram* (Smell)

***Vinathal*:**

'*Vinaathal'* is a method of enquiring about the details of the patient's problem from his own words or from his parents or attenders who are taking care of the patient, when the patient is not able to speak (or) if the patient is a child.

***ENVAGAI THERVUGAL* (Eight tools of examination) is:**

"தரணியிலுள்ள வியாதிதன்னை யட்டாங் கத்தால்
தானறிய வேண்டுவது யேதோ வென்னில்
திரணியதோர் நாடிகண்கள் சத்தத் தோடு
தேகத்தினது பரிசம் வருணம் நாக்கு
இரணமல மூத்திரமா மிவைக ளெட்டும்
இதம்படவே தான்பார்த்துக் குறிப்புங் கண்டு
பரணருளால் பெரியோர்கள் பாதம் போற்றிப்
பண்பு தவறாமல் பண்டிதஞ் செய்வீரே – குணவாகடநாடி

***Naadi* (Pulse)**

In pun, the following types of *Naadi* could be felt. They were,

a) Iyya naadi

b) Vatha kaba naadi

ஐய நாடி:

தானமுள்ள சேத்துமந்தா னிளகில் வெப்பு
சயமீளை இருமல்மந் தார காசம்
ஈளைமுறுஞ் சந்நிவிட தோடம் விக்கல்
இருத்ரோகங் கரப்பான் விரண தோடம் – சதக நாடி

வாத மிகுதியுடன் சீதளம் சேர்ந்தால்:

"இருக்குமந்த வாதத்தில் சேதஞ்சேர்ந்தால்
இளைப்பிருமல் விடசந்நி தோடம் வீச்சு
மருக்கின்ற குளிர்காய்ச்சல் விரண தோடம் – சதக நாடி

Sparism - Test sensation, temperature and nature of the skin

Naa - Test theColour of saliva, colour of sputum and nature of speech.

Niram - Test theVariation in pigmentation of skin.

Mozhi- - *Vaatham* (Normal pitch)

- *Pitham* (High pitch)
- *Kabam* (Low pitched)
- *Thontham* (Mixed all the above)

Vizhi - *Vaatham* (Black in colour, increased lacrimation))

- *Pitham* (Yellow or red in colour)
- *Kabam* (White in colour)

Malam - *Vaatham* (Stools are black in colour and constipated)

- *Pitham* (Yellowish white in colour)
- *Kabam* (White in colour)
- *Thontham* (Mixed colour)

Moothiram

Collection of urine for the determination of *Neerkkuri* and *Neikkuri*, is an important diagnostic method

- ***Neerkkuri***

"வந்தநீர்க்கரிஎடைமணம்நுரைஎஞ்சலென்
றைந்தியலுளவவையறைகுதுமுறையே"
–தேரர்நீர்க்குறிநெய்க்குறிநூல்

Prior to the day of urine examination the patient is instructed to take a balanced diet. The patient should have good sleep. After waking up in the morning, the first urine voided is collected in a clear wide mouthed glass container and is subjected to analysis of "*Neerkkuri*" within one and a half an hour.

- ***Neikkuri***

The collected specimen (Urine) is kept open in a glass dish or china clay container. It is to be examined under direct sunlight, without any shaking of the vessel.

Then add one drop of gingelly oil without disturbing the urinary specimen and the *neikkuri* was noted in direct sunlight and conclude the diagnosis as follows,

Character of *Vaathaneer*

"அரவென நீண்டினஃதே வாதம்

When the oil drop lengthens like a snake, it is called "*Vaathaneer*"

Character of *Pithaneer*

"ஆழி போற்பரவின் அஃதே பித்தம்

When the oil drop spreads like a ring, it is called "*Pithaneer*

Character of *Kabhaneer*

"முத்தொத்து நிற்கின் மொழிவதென் கபமே

When the oil drop appears like a pearl, it is called "*Kabhaneer*"

Character of *Thonthaneer*

"அரவிலாழியும்ஆழியில்அரவும்
அரவின்முத்தும்ஆழியில்முத்தும்
தோயிற்றில்தொந்ததோடங்களாமே"

Snake in the ring, ring in the snake, snake in the pearl and ring in the pearl are the characters of *Thontha neer*.

LINE OF TREATMENT

"நோய்நாடிநோய்முதனாடியதுதணிக்கும்
வாய்நாடிவாய்ப்பச்செயல்"- திருவள்ளுவர்

Thiruvalluvar says in **"*Thirukkural*"** about physician's duty to study the disease, Study the cause, seek subsiding ways and do what is proper and effective.

உற்றவன் தீர்ப்பான்மருந்துழைச் செல்வானென்
றப்பனாற் கூற்றே மருந்து – திருவள்ளுவர்

In Siddha system of medicine, the main aim of the treatment is to cure *Udalpini* and *Manapini*. Treatment is not only for perfect healing but also for prevention and rejuvenation. In siddha system of medicine line of treatment are as follows,

- *Neekam* (Treatment)
- *Niraivu* (Rejuvenation)
- *Kappu* (Prevention)

***Neekam* (Treatment)**

- விரேசனம்
- உள்மருந்து
- வெளிமருந்து
- பத்தியம்

***Virechanam*:**

Siddha system of medicine is based on three humours and hence the treatment is mainly aimed to bring the three humours to equilibrium state and thereby restoring the physiological condition of the seven thathus.

"துகின்ற மலக்கட்டை யொழிய வைத்தால்
உடலிலுள்ள வாதையெலா மொடுங்கிப் போகும்

Internal medicine:

The medicines which are taken internally are called as internal medicines. These are classified into 32 types, e.g. *surasam, saaru, pittu, vadagam* and *chooranam*

External medicine:

The medicines which are applied externally are called as external medicines. These also classified into 32 types, e.g.*kattu, patru, otradam, vedhu* and *thokkanam.*

According to text *sinthamani- gantharuvathathai ilambagam*- 324 management of wound described as follows:

"நெய்க்கிழி வைக்கப்பட்டார், நெய்ப்பத்தல் கிடத்தப்பட்டார்
புக்குழி எஃகம்நாடி இரும்பினால் போழப்பட்டார்"

"முதுமரப்பொந்துபோல முழுமெய்யும் புண்களுற்றார்க்கு
இது மருந்தென்ன நல்லார் இழுதுசேர் கவளம்வைத்து"
-(சிந்தாமணி-காந்தருவதத்தை இலம்பகம் 324)

When there is a traumatic injury in the body the following treatments and therapies can be followed,

1) *Nei kizhi*: A cloth bundled with herbs, which is soaked with heated medicated oil and given foementation.
2) *Ennai patharil kidathal*: The affected person is made to lie down into a tub filled with medicated oil.
3) Removal of foreign particles: When there is a foreign particle at the site of wound like iron or any other metallic object, it is cut and cleaned as per procedure.
4) Application of medicines.
5) Covering the wound: The wound is covered with a small corpet made out of rat hair.

***Anubanam*:**

அனுபானத்தாலே யவிழ்தம் பலிக்கும்
இனிதான சுக்குஇஞ்சி – பினிமுதுகால்
கோமயம்பால் முலைப்பால் கோநெய்தேன் வெற்றிலைநீர்
ஆமிதையா ராய்ந்து செய்யலாம் – தேரையர் வெண்பா

***Pathiyam* (Dietary Regimen):**

In mild conditions of the disease, salt and tamarind can be taken in little quantities. When the condition is severe, tamarind should be avoided and salt must be consumed after frying.

"பத்தியத்தினானே பலனுண்டாகும் மருந்து
பத்தியங்கள் போனால்பலன் போகும் பத்தியத்தில்
பத்தியமே வெற்றி தரும் பண்டிதர்க்கு ஆதலினால்
பத்தியமே உத்தியென்று பால். – தேரையர் வெண்பா

***Niraivu* (Rejuvenation)**

Substances used for neutralising the three humours are**:**

ஒன்றிய வாதபித்த கபமிவை யுயராவண்ணம்
நன்றது கறிகளெல்லாம் நாளுமே சமைப்பராய்ந்தோர்
தின்றிடு மிளகு மஞ்சள் சீரகமுயர்ந்த காயம்
வென்றிகொள் சுக்கோடேலம் வெந்தயமுள்ளி சேர்த்தே
– பதார்த்த குணசிந்தாமணி

The patients are well motivated. The nature and course of the disease is explained to them, Life-style modification advised.

***Kappu* (Prevention)**

Ideal measures mentioned in the Siddha classical text *Pathartha guna chinthamani* for healthy living as below,

"திண்ணமிரண்டுள்ளே சிக்க வடக்காமற்
பெண்ணின்பா லொன்றைப் பெருக்காமல் உண்ணுங்கால்
நீர்சுருக்கி மோர்பெருக்கி நெய்யுருக்கி யுண்பவர்தம்
பேருரைக்கிற் போமே பிணி

"ஆறுதிங்கட் கொருதடவை வமனமருந் தயில்வோம்
அடர்நான்கு மதிக்கொருகாற் பேதியுறை நுகர்வோம்
தேறுமதி யொன்றரைக்கோர் தரநசியம் பெறுவோம்
திங்களரைக் கிரண்டுதரஞ் சவரவிருப் புறுவோம்
வீறுசதுர் நாட்கொருகால் நெய்முழுக்கைத் தவிரோம்
விழிகளுக்குஞ் சனமூன்று நாட்கொருகா லிடுவோம்
நாறுகந்தம் புட்பமிவை நடுநிசியில் முகரோம்
நமனார்க்கிங் கேதுகவை நாமிருக்கு மிடத்தே.

MODERN ASPECT

MORDEN ASPECT

STRUCTURE OF SKIN:

Skin is not an inert wrapping but a dynamic membrane consisting of large number of structures and capable of performing numerous functions. It is the largest body organ contributing more than 15 percent of the body weight. It consist of three layers,

- Epidermis
- Dermis
- Subcutaneous tissue

Epidermis:

Epidermis is 0.5 mm to approximately 2 mm in thickness and is composed of various layers which are as follows from outward to inward

- Stratum corneum
- Stratum lucidum(only palm and sole)
- Stratum granulosum
- Stratum spinosum
- Stratum germinativum

1. Stratum germinativum:

It (Basal cell layer) is the innermost layer of the epidermis. The major cells of this layer are keratinocytes which are columnar in shape and wedge in between these cells are melanocytes and Langerhans cells. The keratinocytes keep on dividing and move outwards undergoing change in shape, size and constituents. This process is known as "keratinization". The skin is being shed off every day unseen to the naked eyes and the whole epidermis is replaced in about a month time. Melanocytes synthesize and distribute melanin to keratinocytes and are responsible for the complexion of an individual. Langerhans cells are the immunogenic cells.

2. Stratum spinosum:

It (Prickle cell layer) is so named due to the spine like appearance of the cell margins in histologic sections. The spines like structures promote adhesion of epidermal cells and resist mechanical stresses. The cells in this layer contain bundles of keratin filaments.

3. Stratum granulosum:

It (Granular cell layer) has 3-4 layers of elliptical cells which contain prominent basophilic kerato-hyalin granules.

4. Stratum lucidum:

It is present only on palms and soles and is situated between stratum granulosum and stratum corneum.

5. Stratum corneum:

It is compossed of multiple layers of flattened, dead horny cells which are the largest epidermal cells. These cells provide protection and act as barrier to the environment.

Epidermmal appendages:

- Sebaceous glands
- Sweat glands
- Hair
- Nails

Dermo-epidermal junction (Basement membrane)

The dermo-epidermal junction forms an extensive interface between the epidermis and the dermis which play a key role in epidermal dermal interactions. It consist of several planes, i.e. lamina lucida (basal portion of keratinocytes), lamina densa and the fibro reticularis. It provides support for epidermis and serves as a semipermeable barrier.

Dermis:

It varies in thickness from 1mm on the eyelid and 5mm on the back. It is a complex system consisting of a supporting matrix, several fibrous and filamentous tissue, epidermally derived appendages, cellular components like fibroblasts, mast cells, macrophages, blood borne cells (lymphocytes, plasma cells, other leukocytes) and nerve and vascular networks. The dermis consist of,

- Papillary dermis
- Reticular dermis

i. Ground substance or the supporting matrix:

It consist of acid mucopolysaccharides and proteins. The main fibrous connective tissues of the dermis are collagen and elastic fibers. Collagen fibers are soft and flexible but strong and inelastic. The elastic fibers form a continuous network throughout the dermis and extend from dermo-epidermal junction to the subcutis and provide elasticity to the skin. Collagen fibers account for 75% and elastic fibers 3% of the dry weight of the skin.

ii. The cellular components of the dermis:

These are fibroblasts, mast cell, macrophages, monocytes and dendrocytes. Fibroblasts are the most common cells found in the dermis. They synthesize and degrade fibrous and nonfibrous proteins of the connective tissue and the matrix. Mast cells are present in large numbers in the papillary dermis around the appendages and blood vessels. They liberate histamine and other mediators in IgE mediated hypersensitivity reactions. The monocytes, macrophages and dendrocytes are immunogenic cells and participate in various immune mediated reactions.

iii. Vascular network:

The skin has rich supply of vascular network. Blood vessels from two plexuses, i.e. the superficial plexus in the papillary dermis and deep plexus in the lower part of the reticular dermis adjoining the subcutaneous tissue around the adnexa. Lymphatics roughly parallel the major vascular plexuses and clear the tissues of unwanted material.

iv. Nerve network:

The network of nerve in the skin consists of somatic sensory fibres and sympatheticautonomic fibres. Sensory fibres perceives the sensation of touch, pain, temperature, itching and mechanical stimuli while autonomic motor fibers control cutaneous vascular tone, pilomotor responses and sudoromotor activity. The smooth and involuntary muscles of the skin occur as arrector pili, tunica dartos of the external genitalia and in the areola of the nipples.

Subcutaneous tissue (Hypodermis)

The subcutaneous tissue consist of lobules composed of adipocytes (fat cells) separated by thin fibrous septa through which small vessels pass. Adipocytes has a cytoplasm with membrane bound lipids that displace the nucleus to the periphery. Subcutaneous fat act as shock absorber, insulator for heat, stores triglycerides which serve as a source of energy upon break down.

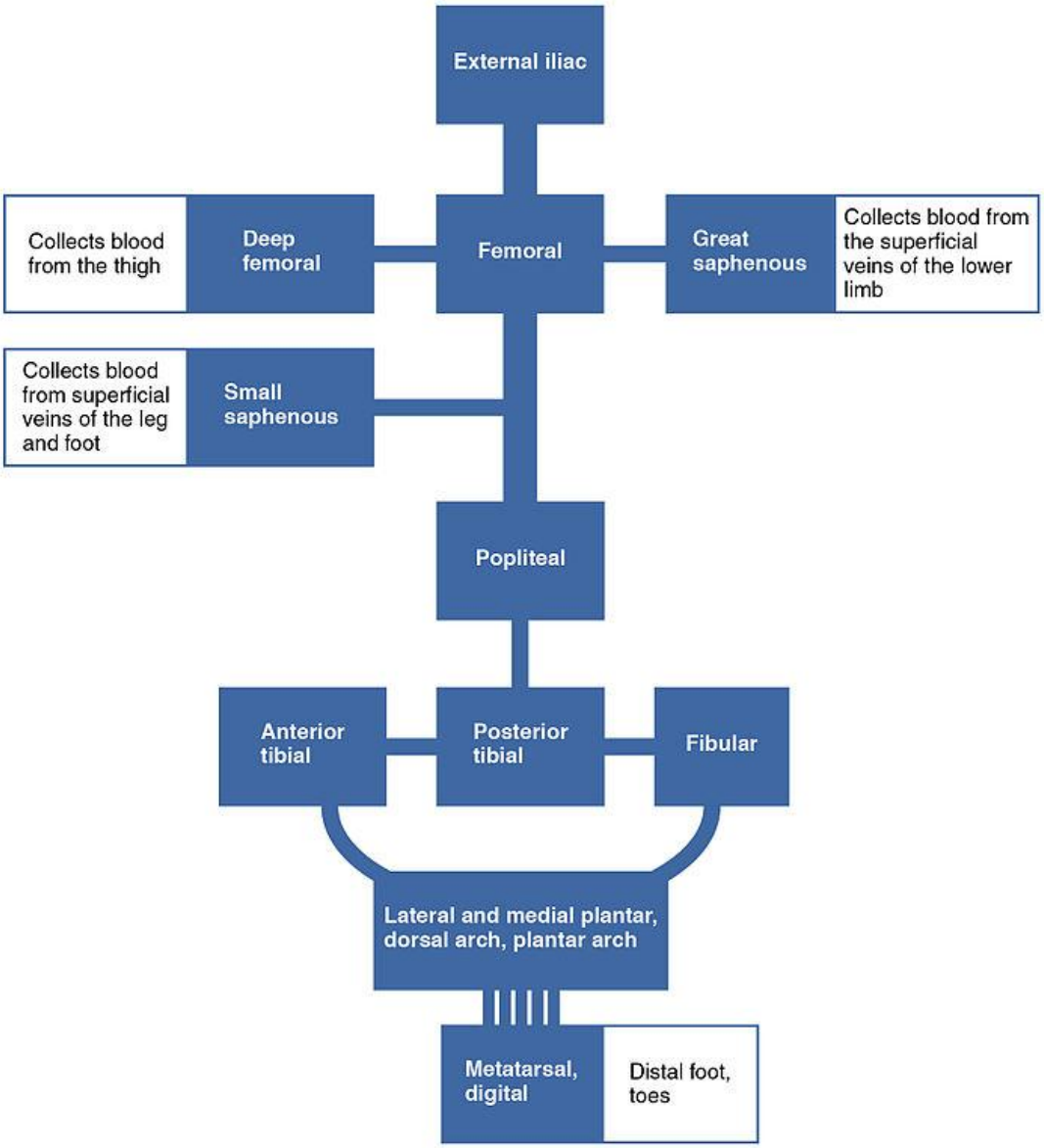
Functions of the skin:

- Protection (From physical, chemical and biological injuries)
- Perception (Sensation like touch, pain, temperature and vibration)
- Temperature regulation (Through eccrine sweat glands and rich blood supply)
- Barrier function (Act as permeability barrier)
- Secretory function (Synthesis of vitamin D_3)
- Storage function (Subcutaneous fat stores energy and other compounds)
- Excretory function (Some harmful substances are excreted through skin)
- Immunological function (Antigen specific cell responses are carried out in the skin)
- Cosmetic function (Colour and texture of the skin along with hair and nail play an important role in aesthetic appeal of an individual)

VENOUS DRAINAGE OF LOWER LIMB:

Consideration of the venous drainage is of great importance because in the lower limb venous blood has to ascend against gravity. This is aided by a number of local factors, the failure of which gives rise to varicose vein. The veins are classified into 3 groups:

- Superficial veins
- Deep veins
- Perforating veins



a. Superficial veins:

They include the great and small saphenous veins and their tributaries. They lie in the superficial fascia, on the surface of the deep fascia. They are thick-walled because of the presence of smooth muscle and some fibrous and elastic tissues in their walls. Valves are more numerous in the distal parts of these veins than in their proximal parts. A large proportion of their blood is drained into the deep veins through the perforating veins

i) Long saphenous vein:

This is the largest and longest superficial vein of the lower limb (Saphes=easily seen). This vein begins on the dorsum of the foot by union of the medial end of the dorsal venous arch with the medial marginal vein. It ascends in

front of the medial malleolus. In the lower one-third of the leg, it passes obliquely across the medial surface of the tibia. In the upper two-thirds of the leg, the vein ascends along the medial border of the tibia, to the posteromedial side of the knee. In the thigh, it inclines forwards to reach the saphenous opening where it pierces the cribriform fascia and opens into the femoral vein. Before piercing the cribriform fascia, it receives three named tributaries corresponding to the three cutaneous arteries, and also many unnamed tributaries.

Surface marking:

Its centre lies 4cm below and 4cm lateral to the pubic tubercle. It is about 2.5 cm long and2cm broad, with its long axis directed downwards and laterally. It can be marked by joining the following points

- First point on the dorsum of foot at the medial end of the dorsal venous arch.
- Second point on the anterior surface of the medial malleolus
- Third point on the medial border of the tibia at the junction of the upper Two thirds and lower one-third of the leg.
- Fourth point at the adductor tubercle.
- Fifth point just below the centre of the saphenous opening.

It contains about 10-20 valves. There is one valve that lies just before the vein pierces the cribriform fascia and another at its termination into the femoral vein.

Tributaries:

- At the commencement- Medial marginal vein from the sole.
- In the leg- It communicates freely with the small saphenous vein and with deep veins.
- Just below the knee- 1) The anterior vein of the leg, 2) The posterior arch vein, 3) A vein from the calf.
- In the thigh- 1) The accessory saphenous vein, 2) The anterior cutaneous vein of the thigh
- Just before piercing the cribriform fascia- 1) Superficial epigastric vein, 2) Superficial circumflex iliac vein, 3) Superficial external pudendal vein.
- Just before termination- Deep external pudendal vein.

- The thoracoepigastric vein runs along the anterolateral wall of the trunk. It connects the superficial epigastric vein with the lateral thoracic vein. Thus very important connection between the veins of the upper and lower limbs.

ii) Small or Short saphenous vein:

The vein is formed on the dorsum of the foot by the union of the lateral end of the dorsal venous arch with the lateral marginal vein. It enters the back of the leg by passing behind the lateral malleolus. In the leg, it ascends lateral to the tendocalcaneus, and then along the middle line of the calf, to the lower part of the popliteal fossa. Here it pierces the deep fascia and opens into the popliteal vein. It drains the lateral border of the foot, the heel and the back of the leg. It is connected with the great saphenous and with the deep veins and is accompanied by the sural nerve.

Surface marking:

It can be marked by joining the following points,

- A point on the dorsum of the foot at the lateral end of the dorsal venous arch.
- Second point behind the lateral malleolus.
- Third point just lateral to the tendocalcaneus above the lateral malleolus.
- Fourth point at the centre of the popliteal fossa.

Just before piercing the popliteal fascia, it may give a communicating branch to the accessory saphenous vein.Sometimes the whole of the small saphenous vein opens into the great saphenous vein through the accessory saphenous vein. Occasionally the small saphenous vein ends below the knee either in the great saphenous vein or in the deep muscular veins of the leg.

b. Deep vein:

These are the anterior and posterior tibial, peroneal, popliteal and femoral veins and their tributaries. They accompany the arteries and are supported by powerful surrounding muscles. The valves are more numerous in deep veins than in superficial veins. They are more efficient channels than the superficial veins because of the driving force of muscular contraction.

c. Perforating veins:

These are connects the superficial veins with the deep veins. These are classified into 2 groups:

- Indirect perforating vein
- Direct perforating vein

Indirect perforating veins:

These are connecting the superficial veins with the deep veins through the muscular veins.

Direct perforating veins:

These are connecting the superficial veins directly with the deep veins. The great and Small saphenous veins are the largest direct perforators. The small perforating veins are summarised below,

- In the thigh- The adductor canal perforator
- Below the knee- One perforator connects the great saphenous vein or the posterior arch vein with the posterior tibial vein.
- In the leg- 1) A lateral perforator, 2) The upper medial perforator, 3) The middle medial perforator and 4) The lower medial perforator.

Factors helping venous return:

General factors:

- Negative intrathoracic pressure which is made more negative during inspiration
- Arterial pressure and overflow from the capillary bed
- Compression of veins accompanying arteries by arterial pulsation
- Valves which support the long column of blood and maintain a unidirectional flow.

Local factors:

- Venous: Veins of lower limb are more muscular than the veins of other part of the body. They have number of valves. Superficial veins are connected to deep veins by perforators.

- Muscular: When the limb is active, muscular contraction compresses the deep veins and drives the blood in them upwards.
- Fascial: The tight sleeve of deep fascia makes muscular compression of the veins much more effective by limiting outward bulging of the muscles.

LEG ULCERS:

Leg ulcers are common medical condition, affecting 3% to 5% of the population over the age of 65. The cause of the leg ulceration is venous insufficiency alone in 45% to 60% of cases, arterial insufficiency in 10% to 20%, diabetes mellitus in 15% to 25% or combination in 10% to 15%. Smoking and obesity increase the risk for ulcer development and persistence, independent of the underlying cause. Defining the cause of the leg ulceration is important in healing the ulceration. However except in the cause of significant arterial insufficiency, most leg ulcers can be healed without treating the anatomic underlying cause.

The wound healing response is complex, involving intricate interactions between different cell types, structural proteins, growth factors and proteinases. Normal wound repair consist of three phases- inflammation, proliferation and remodelling. Those occur in a predictable sequence and comprise a series of cellular and bio chemical events. Abnormalities in any one of these components can produces delayed or ineffectual wound healing.

CLASIFICATION OF ULCER:

Mainly ulcers are classified in to two types

- Clinically
- Pathologically

I. Clinically

- Healing ulcer
- Spreading ulcer
- Callous or chronic ulcer

II. Pathologically

- Non-specific ulcers – traumatic
  - Arterial
  - Venous

- Neurogenic (trophic)
- Associated with malnutrition
- Ulcer due to other diseases

- Specific ulcers (eg. Tuberculous, syphilitic)
- Malignant ulcers (eg. Epithelioma, marjolins ulcer)

VARICOSE ULCER

Synonyms – post thrombotic ulcer, gravitational ulcer

Definition:

Venous ulcer also known as stasis ulcer is the most common aetiology of lower extremity ulceration. Venous ulceration result from increased pressure in the venous system of the lower limb. Most common cause is insufficiency of the valves in the deep venous system and lower perforating veins of the lower leg. This is mostly occurs in the age of 40 to 60 yrs. Women are most commonly affected than men.

Epidemiology:

The extrapolated prevalence rate of varicose vein in India providing warning is about 47,928,177 in statistics. According to another estimate 15 to 20% of population in India is suffering vein disease.

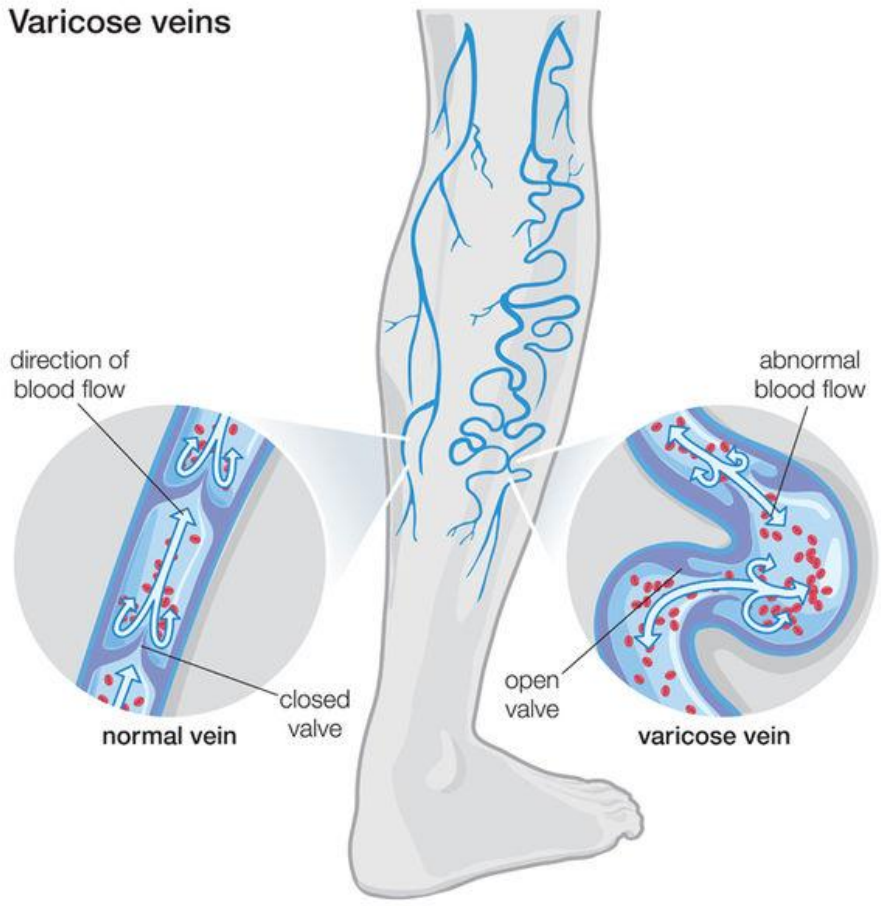
Despite being more common in elderly persons, with a peak of prevalence in individuals aged between 60 and 80 years, 22% of those affected are approximately 40 years of age, while 13% develop VU before they reach 30 years of age, evidencing the losses that this disease causes in work production. Of all lower limb ulcers, approximately 70 to 80% are caused by CVI.

The first venous stasis ulcer episode occurs in average, five years after the diagnosis of CVI and, in patients with VU, 47% have already had two or more ulceration episodes, whereas 21% of them have already had six or more episodes. The annual recurrence rate varies from 33 to 42%. In general, 60% of the ulcers remain for a period of 6 months or longer, and over 40% of them persist for more than one year. The mean duration is 6 to 9 months, varying from 4 weeks to 72 years.

Causes:

Varicose vein:

- Incompetence of valves - Sapheno-femoral junction(SFJ)
  - Sapheno-popliteal junction(SPJ)
  - Perforator
- Reflux in superficial veins - Long saphenous vein (LSV)
  - Short saphenous vein (SSV)
- Reflux in deep veins - Femoral vein
  - Popliteal vein



Classification of causes:

- Primary - Congenital
- Secondary - Pregnancy
  - Abdominal or pelvic mass
  - Ascites
  - Obesity
  - Constipation
  - Thrombosis of leg veins
  - Spend long period of time standing

Predisposing factors:

- Old age
- Obesity
- Female
- Pregnancy
- Hypertension
- Lower socio-economic status
- Previous injury
- H/O Deep vein thrombosis
- Congestive heart failure
- Anaemia
- Zinc deficiency
- Defective fibrinolytic system

Classification:

a) **Clinical**
- C0: No visible or palpable sings of venous disease
- C1: Telangiectasies or reticular vein
- C2: Varicose veins
- C3: Oedema
- C4: Pigmentation or oedema, Lipodermatosclerosis
- C5: Healed venous ulcer
- C6: Active venous ulcer

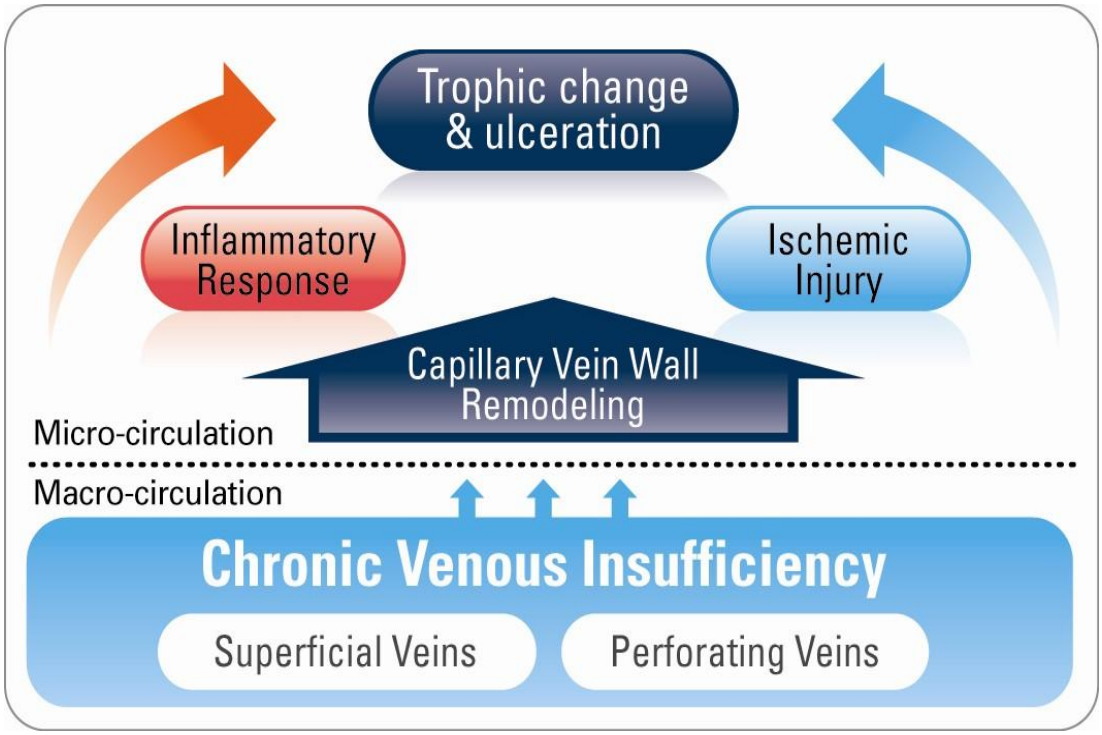
b) Etiological – Congenital

- Primary
- Secondary

c) Anatomic – Superficial veins

- Perforator veins
- Deepvein

d) Pathophysiology:



Venous blood from lower limb are pumped into heart through various factors, one of the main factor is calf muscle pumping. With each contraction of the calf, blood should be pumped to the heart (muscle pump). Intact valves in the lower leg are required to prevent this pumped blood from reflexing out through the perforators in to the superficial system. The hypertrophy of these superficial veins is marked by the development of varicose veins. Increased pressure on the iliac veins from pregnancy or obesity or simple inactivity may also result in the appearance of venous insufficiency as well. The valvular insufficiency results in disorder in the venous and capillary circulation in the leg. Valve insufficiency may occur from prior thrombophlebitis or congenital weakness.

Clinical features:

- Ulcer present in lower part of the leg on medial side. These are never seen above the junction of the middle and upper third of the leg.
- Varicose ulcer can be of any shape and size.
- The ulcer is painful in the beginning but in chronic it becomes painless.
- The discharge is seropurulent with occasional trace of blood.
- The surrounding skin is shows signs of chronic venous hypertension (pigmentation, induration and tenderness)
- Regional lymph nodes (inguinal nodes) are only enlarged if the ulcer becomes infected.
- Squamous carcinoma can be arising from the margin of the long standing venous ulcer. When the edge of the ulcer is raised and everted or somewhat different from described above should arouse suspicion of malignancy.
- The base of the ulcer becomes hard. The malignant ulcer is called marjolin's ulcer.
- Discomfort and tenderness of the skin.
- Pigmentation and eczema exist for months or years before a ulcer develops.
- Swelling that subsided with elevation
- Ulcer may appear on the background of stasis dermatitis.
- Granulation tissue and fibrin present

- Oedema and fibrosis present over the medial aspect of the ankle and lower third of the shin.
- Following a minor trauma a macular haemorrhage appears, this is the premonitory sign often impending ulceration.
- Lower extremities varicosities present

On physical examination:

- Varicose ulcer can be of any shape and size.
- The edges are slopping and pale purple- blue in colour.
- The margin is thin and blue of growing epithelium.
- The floor is formed by pale granulation tissue.
- The ulcer is usually shallow and flat and never penetrates the deep fascia.
- The discharge is seropurulent with occasional trace of blood.
- The base of the ulcer is fixed to the deeper structures. Granulation tissue and fibrin present in base of the ulcer
- The surrounding skin is shows signs of chronic venous hypertension (pigmentation, induration and tenderness)
- Venous dermatitis with hyperpigmentation and hemosiderosis or haemoglobin deposition in the skin.
- There may be scare of previous ulcer
- Regional lymph nodes (inguinal nodes) are only enlarged if the ulcer become infected.
- Lower extremities varicosities present
- Swelling of lower limb
- Lipodermatosclerosis with thickening and fibrosis of normal adepose tissue under skin.

Complications:

- Cellulitis
- Osteomyelitis
- Malignant changes
- Haemorrhage
- Periosteitis

DIFFERENTIAL DIAGNOSIS

Traumatic ulcer –this ulcer can be caused by either mechanical, physical or Chemical injury. This ulcers heels quickly unless supervened by infection or ischaemia. Which may turn this ulcer to chronicity.

Ischaemic or arterial ulcer - this ulcer due to peripheral arterial diseases, and poor Peripheral circulation.This is more often seen in older people and younger men between 20 to 40 yrs of age. In this ulcer patches of dry gangrene may be present along with ulcer. This ulcers are occurs on the anterior and outer aspect of the leg, dorsum of the foot, on the toes or the heel. Pain is main complaint of this disease. An arterial ulcer occurs below the medial malleolus. There is history of intermittent claudication and resting pain in majority of cases. If the leg is kept elevated above the heart level the ulcer shows no sign of healing and patient will complaint of pain in this position. On examination these ulcers are punched out with destruction of deep fascia. Tendons, bones, and under lying joints may be exposed on the floor of the ulcer. Which covered by minimal granulation tissue. Presence of ischaemic changes can be detected on the foot (pallor, dry skin, loss of hair, fissuring of nails). Pulse of dorsalis pedis artery this always either feeble or absent.

Trophic ulcer (neurogenic) – these ulcer have punched out edge with slough in the floor thusresembling a gummatous ulcer. (eg. Bed sore and perforating ulcers). These ulcer develop as the result of repeated trauma to the in sensitive part of the body. These ulcers are commonly seen on the heel and the ball of the foot. When the patient is ambulatory, on the buttock and on the back on the heel when the patient is non ambulatory. The ulcers start with callosity under which suppuration takes place, the pus comes out and the central hole forms the ulcer which gradually burrows through the muscles and tendons to the bone. Floor is covered with offensive slough and tendons and even bones can be seen here. The surrounding skin has no sensation. The cause may be spinal or leprosy or peripheral nerve injury, diabetic neuropathy, tabes dorsalis, transvers myelitis or meningomyelocele.

Tuberculous ulcer – this mostly result from bursting of caseous lymph nodes are from abseess from bone and joint tuberculosis and breaks out on the surface. Ulcer is slightly painful usually seen in the neck and groin. The features of ulcer is its edge which is thin, reddish blue and determined, pale granulation tissue with scanty serosanguineous discharge in the floor and slight induration at the base. The regional lymph node are enlarged, non-tender and matted.

Syphilitic ulcer – hard chancre appears on the external genitalia 3 or 4 weeks after infectionin the first stage of this disease. It is painless and possesses a characteristic indurated base, which feels like a button. Lymph nodes are enlarged. Extra genitalia chancres which are seen in the nipple, lip, tongue and anal canal are not often indurated.

Meleney's ulcer – these ulcers are seen the postoperative wounds either after the operation for perforated viscus or for drainage of emphyema throacis. This type of ulcer is due to symbiotic action of micro aerophilic non haemolytic streptococci and haemolytic staphylococcus aureus. It is a grangenous wound fallowing any operation. Rarely is it seen on the leg or on the dorsum of the hand. It is spreading ulcer which is painful with signs of toxaemia. The floor contains aboundent foul smelling granulation tissue with copious seropurulent discharge. It is surrounded by deep purple zone, which in turn is surrounded by an outer zone of erythema.This particular condition is painful, toxaemic and the generalcondion deteriorates without treatment. If it is not treated the patient's general condition deteriorates and he will die ultimately.

Examination:

- Abdomen mass
- Peripheral pulses
- Pattern of varicosities – LSV/ SSV
- Trendelenburg test

Investigation:

- Doppler
- Air plethysmography – Venous refilling time
- Venogram
- Duplex scan
- USG Abdomen/pelvis
- Ulcer – Swab culture, TWDC

Treatment:

a) Non –surgical – Compression stockings
- Wound dressing
- Weight reduction
- Pharmacotherapy
- Leg elevation at rest

b) Surgical - High saphenous ligation
- Endovenous laser ablation
- Endovenous radio-frequency ablation
- Sclerotherapy

Prevention:

- Be active, moving the leg muscles keeps the blood flowing.
- Keep your blood pressure under control. Work with your doctor.
- To temporarily relieve symptoms, lie down and raise your legs at least six inches above the level of your heart. Do this for ten minutes a few times each day.
- Maintain a normal body weight.
- Wear prescription compression stockings as specified by your doctor.

DRUG REVIEW

INTERNAL MEDICINE

KUKKIL

Botanical Name : *Shorea robusta, Gaertn.f.*

English Name : Sal tree

Family : Dipterocarpaceae

Organoleptic Character

Taste : Kaippu

Potency : Veppam

Division : Kaarpu

பொதுகுணம்:

"பெரும்பாடு மேகம்போம் பேராதுடலில்
அரும்பிய புண்ணாறுமிவை யல்லால்-குரும்பாம்
எலும்புருக்கி புண்சீழும் ஏகும் உலகில்
சலம்பருகுங் குங்கிலியத் தால்.

Actions:

- Stimulant
- Expectorant
- Diuretic

PARANGIPATTAI

Botanical Name : *Smilax china.Linn*

English Name : China root

Family : Liliaceae

Organoleptic Character

Taste : *Inippu*

Potency : *Thatpam*

Division : *Inippu*

பொது குணம்:

"தாகம் பலவாதந் தாதுநட்டம் புண்பிளவை
மேகங் கடிகிரந்தி வீழ்மூலந் –தேகமுடன்
குட்டை பகந்தமேற் கொள்வமனம் போம்பறங்கிப்
பட்டையினை யுச்சரித்து பார். - தே.கு

Chemical constituents:

- Sarasapogenin
- Cortisone

Actions:

- Alterative
- Antisyphilitic
- Aphrodisac
- Depurative

GANDHAGAM

English Name : Sulphur

Organoleptic Character

Taste : Kaippu, Thuvarppu

Potency : Veppam and Thatpam

பொது குணம்:

"நெல்லிக்காய்க்கந்திக்குநீள்பதினெண்குட்டமந்தம்
வல்லைகவிசைகுன்மவாயுகண்ணோய்–பொல்லா
விடக்கடிவன்மேகனோய்வீறுசுரம்பேதி
திக்கிரசுணீகபம்போந்தேர்"

Action:

- Laxative
- Tonic
- Antiseptic
- Diaphoretic
- Cholagogue

MILAGU

Botanical Name : Piper nigrum

English Name : Black pepper

Family : Piperaceae

Organoleptic Character

Taste : Kaippu, kaarppu

Potency : Veppam

Division : Kaarppu

பொது குணம்:

"தீயாகி யெங்கும் திரியுமதை யாவத்து
மோயாம லெப்படியு முண்டாக்காற்- பாயாது
போந்திமிர்வா தங்கிரந்தி புண்ணீரும் மண்ணவர்க்கும்
காந்திமெய்வா தச்சலுப்பைக் காய்

Chemical Constituents:

A volatile alkaloid Piperine or Pipirine 5-9%, Piperidine or Piperidin 5%, Abalsamic volatile essential 1-2%, fat7%.Mesocarp contains chavicin, a balsamic volatile oil, starch, gum, Piperrettine, Piperanine, Pipericide Sarmentine, Eugenol.

Ref: Indian Herbal Pharmacopoeia, P – 321.

Actions:

- Carminative
- Pungent
- Antiperiodic
- Analgesic
- Anti- inflammatory
- Antioxidant
- Cyclooxygenase inhibitory activity

Ref: Indian Herbal Pharmacopoeia, P – 324 Database, Vol. – 190.

THIPPILI

Botanical Name : Piper longum

Synonym : Charica roxburgii

Family : Piperacae

Organoleptic Character

Taste : Kaarppu

Potency : Veppam

Division : Kaarppu

பொது குணம்:

"கட்டி யெதிர்நின்று கடுநோயெல் லாம்பணியும்
- திட்டி வினையகலும் தேகமெத்த புட்டியாம்
மாமனுக்கு மாமனென மற்றவர்க்கு மற்றவனாங்
காமமெனுந் திப்பிலிக்கும் கை – தேரன் வெண்பா

Chemical Constituents:

Piperine (4 – 5%), Volatile Oil, Piperlonguminine,Piplartine, Sesamin, Terpenoids, Resin, Piperundecalidine.

Ref: Indian Herbal Pharmacopoeia revised – 2002, P – 310, 311.

Actions:

- Stimulant
- Carminative
- Alterative

KUROSANI OMAM

Botanical Name : *Hyocyamus niger.Linn*

English Name : Henbane seed, Black henbane

Family : Solanaceae

Organoleptic Characters

Taste : Kaarpu, Kaippu.

Potency : Veppam

Division : Kaarppu

பொது குணம்:

"வெகுமூத் திரம்வாதம் வீரியநட் டம்புண்
உகுபேதியுட்கடுப்பினோடே மிகுகரப்பான்
தீராக் கபமிவைபோம் செய்யகு ரோசானியென்றால்
வாரா மயக்கமுறு மால் – (அ.கு)

Chemical Constituents:

- Hyoscyamine
- Hyoscyine
- Scopolamine

Action:

- Antispasmodic
- Anodyne
- Hypnotic
- Sedative
- Mild diuretic

JATHIKKAI

Botanical Name **:** *Myristica fragrans Houtt*

English Name **:** Nut meg

Family **:** Myristicaceae

Organoleptic Characters

Taste **:** Thuvarpu, Karppu.

Potency **:** Veppam

Division **:** Kaarppu

பொது குணம்:

"தாது நட்டம் பேதி சருவாசி யஞ்சிர நோய்
ஓதுசுவாசங் காசம் உட்கிரணி – வேதோ
டிலக்காய் வரும்பிணிபோம் ஏற்றமயல் பித்தங்
குலக்கா யருந்துவர்க்குக் கூறு

Chemical Constituents:

- Myristicine

Action:

- Stimulant
- Carminative
- Narcotic
- Aromatic
- Aphrodisiac
- Tonic

JATHIPATHIRI

Botanical Name : *Myristica fragrans Houtt*

English Name : Arillus of the nut(Maca)

Family : Myristicaceae

Organoleptic Characters

Taste : Karppu, Thuvarpu.

Potency : Veppam

Division : Kaarppu

பொது குணம்:

"சாதிதரும் பத்திரிக்குத் தாபச் சுரந்தணியும்
ஓதுகின்ற பித்தம் உயருங்காண் – தாதுவிர்த்தி
யுண்டாங் கிரகணியோ டோதக் கழிச்சலறும்
பண்டாங் குறையே பகர் – (அ.கு)

Action:

- Stimulant
- Carminative
- Aphrodisiac
- Hypnotic

THANDRIKAI

Botanical Name : Terminalia Bellerica. Roxb.

English Name : Beleric Myrobalan.

Family : Combretaceae

Organoleptic Characters

Taste : Thuvarppu

Potency : Veppam

Division : Inippu

பொது குணம்:

சிலந்திவிடம் காமியப்புண் கீழான மேகங்
கலந்துவரும் வாதபித்தங்காலோ டலாந்துடலில்
ஊன்றிக்காய் வெப்ப முதிரபித்துங் கரக்குந்
தான்றிக்காய் கையிலெடுத்தால்.

Chemical constituents:

Main chemical constitutes are tannins mainly include ß- sitosterol, gallic acid, ellagic acid, ethyl gallate, galloyl glucose and chebulaginic acid.

Action:

Tannins: It shows scavenging activity against mitochondrial lipid peroxidation. It causes significant decrease in cholesterol level and it also shows antimicrobial activity against bacteria and virus with a significant inhibition of microsomal lipid peroxidation and reduction in triglyceride levels in liver and reduction in total acidity and peptic activity and increase in mucin content.

Ref: Indian Herbal Pharmacopoeia.

SEERAGAM

Botanical Name : *Cuminum cyminum.Linn*

English Name : Cumin seeds or fruit

Family : Apiaceae

Organoleptic Characters

Taste : Karppu, Inippu

Potency : Thatpam

Division : Inippu

பொது குணம்:

"பித்தமெனு மந்திரியைப் பின்னப் படுத்தியவன்
சத்துருவை யுந்துறந்து சாதித்து – மந்தனெனும்
ராசனையு மீவென்று நண்பைப் பலப்படுத்தி
போசனகு டாரிசெயும் போர் – (தேரன் வெண்பா)

Chemical Constituents:

- Thymene
- Cuminol
- Cymene

Action:

- Carmiative
- Stimulant
- Stomachic
- Astringent

CHITRARATHAI

Botanical Name : *Alpinia officinarum*

English Name : Lesser galangal

Family : Zingiberaceae

Organoleptic Characters

Taste : Karppu

Potency : Veppam

Division : Karppu

பொது குணம்:

"வாதபித் தங்கரப்பான் வாதஞ் சிரோரோகஞ்
சேர்ந்தகப முத்தோடஞ் சீதமொடு – நேர்ந்தசுரம்
மற்றரத்தைக் காட்டி வருமிரும லுந்தீரும்
சிற்றரத்தை வன்மருந்தால் தேர் – (தே.கு)

Chemical Constituents:

- Galangol
- Galangin

Action:

- Expectorant
- Febrifuge
- Stomachic

NELLIMULLI

Botanical Name : Phyllanthus Emblica

English Name : Indian gooseberry

Family : Euphorbiaceae

Organoleptic Characters

Taste : Pulippu, Thuvarppu, Inippu

Potency : Thatpam

Division : Inippu

பொது குணம்:

நெல்லிக்கய்க் குப்பித்தம் நீங்கு மதன்புளிப்பால்
செல்லுமே வாதமதிற் சேர்துவரால் – சொல்லுமையம்
ஓடுமிதைச் சித்த்த்தில் உண்ண அனலுடனே
கூடுபிற மேகமும் போங்கூறு.

Chemical Constituents:

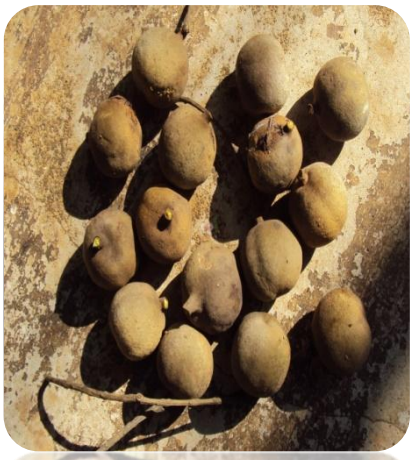
Ascorbic acid, high density of ellagitannins such as emblicanin A (37%), emblicanin B (33%), Punigluconin (12%) and pedunculagin (14%). Polyphenols: Flavonoids, Kaempferol, ellagic acid and gallic acid.

Action:

- Astrigent
- Diuretic
- Laxative
- Refrigerant

Internal Medicine

NellikkaiThanni kai



Kurasani OmamChittaratai

Parangi pattai

Kukkil

KanthagamMilaku

Thippili

Sathikkai

Sathipatri

Jirakam

KUKKIL CHOORANAM

EXTERNAL MEDICINES

GINGELLY OIL

Botanical Name : *Sesamum indicum.Linn*

English Name : Sesame

Family : Papillonaceae

Organoleptic Character

Taste : Inippu

Potency : Veppam

Division : Inippu

பொது குணம்:

"புத்திநயனங் குளிர்ச்சி பூரிப்பு மெய்புளகஞ்
- சத்துவங் கந்தி தனியிளமை மெத்தவுண்டாங்
கண்ணோய் செவிநோய் கபாலவழல் காசநோய்
புண்ணோய்போ மெண்ணெய்யாற் போற்று

Chemical Constituents:

Oleic and Linoleic Acid, Calcium, Phosphorus, Sodium Chloride, Lysine, Methionine, Free Fatty Acid, Oxalate and Aflatoxin B_1

Ref:http://www.indianjournals.com/ijor.aspx?target=ijor:anft&volume=8&issue &article=003

Actions:

- Demulcent
- Laxative
- Nutritive
- Emollient

Ref: Indian Medicinal plants Compendium, Vol. – V, P – 104.

KASUKATTI

English Name : Catechu

Organoleptic Character

Taste : Thuvarpu

Potency : Thatpam

Division : Karpu

Action:

- Astringent.

It cures,

- Eczema
- Diabetes
- Menorrhogia

THURUSU

English Name **:** Copper Sulphate

Organoleptic characters:

Taste **:** Thuvarppu

பொது குணம்:

புண்ணாற்றுங்காமியத்தின்புண்ணாற்றுங்கண்ணோயை
விண்ணேற்றுமுத்தோடவீறடக்குஞ்-சண்ணுகின்ற
வாந்தியொடுபேதிதரும்வாய்நோய்சுரந்தணிக்குங்
காந்திதருந்துரிசுகாண்.

It cures

- Skindisease,
- Indigestion,
- Hepatomegaly,
- Ascites,
- Ulcer,
- Eye disease,
- Diarrhoea

Actions:

- Nutrient
- Astringent
- Antiseptic
- Caustic
- Emetic

KALIPPAKKU

Botanical name : *Areca catechu*

English Name: Areca-nut

Family : Arecaceae

Organoleptic characters:

Taste : Thuvarppu

Potency : Vepam

Division : Kaarppu

பொது குணம்:

களிப்பாக்குத் தின்றக்காற் கண்டத்துட் கோழை
யொளிப்பாபாகக் கட்டுமிஃ துண்மை-தளிர்ப்பான
பித்த அரோசகம்போம் பேதிமிக உண்டாகுஞ்
சித்த மகிழ்ச்சியுறுஞ் செப்பு.

-அகத்தியர் குணவாகடம்

Chemical constituents:

- Lupeol
- Stigmasterol
- Flavonoids
- Carbohydrates

[Ref. Book: Medicinal plants-Dr.M.Daniel]

Actions:

- Stimulant
- Astringent
- Toenifuge

KADUKKAI

Botanical Name : Terminalia chebula. Retz

English Name : Chebulic Myrobalan, Ink nut

Family : Combretaceae

Organoleptic Characters

Taste	**:**	Thuvarppu, Inippu, Pulippukaarppu, Kaippu.
Potency	**:**	Veppam
Division	**:**	Kaarppu

பொது குணம்:

தாடை கழுத்தக்கி தாலு குறியிவிடப்
பீடை சிலிபதமுற் பேதிமுடம் – ஆடையெட்டாத்
தூலமிடி புண்வாத சோணிகா மாலையிரண்
டாலமிடி போம்வரிக்கா யால்.

Chemical Constituents:

The number of glycosides are isolated from Kadukkai, including the triterpenes arjunglucoside I, arjungenin, and the chebulosides I and II. Other constituents include acoumarin conjugated with gallic acids called chebulin, as well as other phenolic compounds including ellagic acid, 2,4-chebulyl-β-D-glucopyranose, chebulinic acid, gallic acid,ethyl gallate, punicalagin, terflavin A, terchebin, luteolin, and tannic acid.[Chebulic acid is a phenolic acid compound isolated from the ripe fruits. Luteic acid can 0be isolated from the bark. T. chebula also contains terflavin B, a type of tannin while chebulinic acid is found in the fruits.

Ref: Indian Herbal Pharmacopoeia.

Action:

- Laxative
- astringent
- Anthelmintic
- Nervine
- Expectorant
- carminative
- appetite stimulant

KADUKKAI POO

Botanical Name	**:**	Terminalia chebula. Retz
English Name	**:**	Flower of Chebulic Myrobalan
Family	**:**	Combretaceae

Organoleptic Characters

Taste **:** Thuvarppu, Inippu, Pulippukaarppu, Kaippu.

Potency **:** Veppam

Division **:** Kaarppu

Chemical Constituents:

- Tannin
- Chebulinic acid
- Gallic acid

Action:

- Laxative
- astringent
- Anthelmintic
- Nervine
- Expectorant
- carminative
- appetite stimulant

VEMBAADAM PATTAI

Botanical name **:** Ventilago madraspatana

English Name **:** Red Creeper

Family **:** Rhamnaceae

Chemical constituents:

- Tannins

Pharmacological activity:

- Anti-Denaturation activity
- Anti-oxidant activity
- Anti-bacterial
- Anti-Inflammation
- Cytotoxic Activity (Anti-cancer)

-Int. J. Pharmacol. Bio. Sci., 5(2), 75-78, 2011.

It cures,

- Itching
- Cutaneous eruption

SANDHANAM

Botanical name : *Santalum album*

English Name : Sandal wood

Family : Santalaceae

Organoleptic characters:

Taste : Siruthuvarppu

Potency : Thatpam,Vepam

Division : Inippu,Kaarppu

பொது குணம்:

கோதில் சந்தனஞ் சீதோணங் கொண்டிருக்கும்
வாதபித்தம் யம் மனப்பிரமை-ஓதுசுரம்
மேகம் தனித்தாகம் வெப்பு சொறி யும்போக்கும்
ஆகந் தனக்குறுதி யாம்

-அகத்தியர் குணவாகடம்

Chemical constituents:

- Santalol

[Ref. Book: Medicinal plants-Dr.M.Daniel]

Actions:

- Alterative
- Astringent
- Diuretic
- Diaphoretic
- Stimulant
- Disinfectant
- Cooling

External Medicine

Vembadam pattai

Kali pakku

Kasikatti

Kadukkai

Thurusu

Sandhanam

Nallenai

Thuvara Ennai

MATERIAL AND METHODS

MATERIALS AND METHODS

STANDARD OPERATING PROCEDURE:

COLLECTION OF RAW DRUGS:

The required raw drugs for the preparation of the trial medicines were procured from a well reputed country raw drug shop**.**

RAW DRUGS IDENTIFICATION AND AUTHENTICATION:

The mineral raw drugs were identified and authenticated by Smt.R.Shakila, RO chemistry, Siddha Central research Institute, Arumbakkam, Chennai-106. The Herbal raw drugs were identified and authenticated by Dr.D.Aravind M.D(s), Assistant professor, Dept. of Botany, National Institute of Siddha, chennai-47. After that the raw drugs were purified as per siddha literature then the trial drugs prepared in Gunapadam laboratory of National Institute of Siddha.

INTERNAL DRUG:

KUKKIL CHOORANAM (Ingredients)

Suthi seitha kukkil *(Shorea robusta)*	-	2 Palam (70gm)
Suthi seitha parangipattai(*Smilax china)*	-	2 Palam(70gm)
Suthi *seitha*gandhagam(sulphur)	-	½Palam(17.5gm)
Milagu(*Piper nigrum)*	-	1Palam(35gm)
Thippili(*Piper longum)*	-	1Palam(35gm)
Kurosani omam(*Hyocyamus niger)*	-	1Palam(35gm)
Jathikkai(*Myristica fragrans)*	-	1Palam(35gm)
Jathipathiri(*Myristicafragrans)*	-	1Palam(35gm)
Thanrikkai thool(*Terminalia bellirica)*	-	1Palam(35gm)
Seeragam(*Cuminum cyminum)*	-	1Palam(35gm)
Chitrarathai(*Alpinia officinarum)*	-	1Palam(35gm)
Nellimulli(*Phyllanthus emblica)* -1Palam(35gm)		

METHOD OF PURIFICATION OF RAW DRUGS:

Purification of Kukkil:

The Kukkil is boiled in tender coconut water.

[Ref: Sarakugalin suthee muraigal page 4]

Purification of Parangi pattai:

It is dried, powdered and then boiled in Steam of milk (Pittaviyal).

[Ref:Sarakugalin suthee muraigal page 11]

Purification of Ganthagam:

Sulphur is placed in an iron spoon. A small quantity of cow's butter is added and the spoon is heated till the butter melts; this mixture is immersed in inclined position in cow's milk. This procedure is repeated for 30 times to get purified sulphur. Each time, fresh milk is to be used.

(Ref: Siddha Materia Medica (Mineral and animal kingdom) Page No: 253)

Purification of Milagu:

Soak in butter milk for a period of one saamam (3 hours) then allow it to dry.

[Ref: Sikicha Rathina Deepam Ennum Vaithiya Nool page 28]

Purification of Thippili:

Soak in juiceof Lime then allow it to dry.

[Ref: Sarakugalin sutheemuraigal page 7]

Purification of Kurosani omam

Put it into sand and mix well then remove the outer covering.

[Ref:Sarakugalin suthee muraigal page 5]

Purification of Jaathikkai:

Remove the outer cover, cut into small pieces and dry it inshadow.

[Ref: Sighitcha Rathan Deepam Ennum Vaithiya Nool, Page: 29]

Purification of Jaathipathiri:

Remove the flowerlets and dry in the shadow.

[Ref:Sighitcha Rathan DeepamEnnum Vaithiya Nool, Page: 29]

Purification of Thandrikkai:

Remove the nut and use the outer covering of the drug.

[Ref: Sarakugalin suthee muraigal page 7]

Purification of Chitrarathai:

Cut the rhizome into pieces and dry it in shadow.

[Ref: Sikicha Rathina Deepam Ennum Vaithiya Nool, page 35]

Purification of Narseeragam:

Dry it shadow for 6hours and fry well.

[Ref: Sarakugalin suthee muraigal page : 6]

Purification of Nellimulli:

Remove the nut and use the fleshy part of the drug.

[Ref: Sarakugalin suthee muraigal Page: 9]

METHOD OF PREPARATION:

Purified raw drugs were dried, pulverized in mortar and filtered with cotton cloth and stored in a container.

EXTERNAL MEDICINE:

THUVARA ENNAI (Ingredients)

Gingelly oil	-	1 padi(1.4 lit)
Kaasukatti(Catechu)	-	1varaagan(3.5 gm)
Thurusu(Copper sulphate)	-	1varaagan (3.5gm)
Kalipaku(*Areca catechu)*	-	1varaagan (3.5gm)
Kadukkai(*Terminalia chebula)*	-	1varaagan (3.5gm)
Kadukkai poo(*Terminalia chebula)*	-	1varaagan (3.5gm)
Vembaadam pattai(*Ventilago madraspatana)*	-	1varaagan (3.5gm)
Santhana thool(*Santalum album)*	-	1varaagan (3.5gm)

METHOD OF PREPARATION:

All ingredients are powdered make it into paste and mixed with oil and then boiled till it attained the consistency.

DRUG STORAGE:

The trial drug *Kukkil chooranam* is stored in a clean and dry glass bottles and *Thuvara Ennai* is stored in a clean and dry narrow mouthed bottles.

DISPENSING:

The Powder is given in packet. Oil is given in pet bottles.

PRECLINICAL STUDY:

CHEMICAL EVALUATION

Experimental procedure:

5 g of Kukkil Chooranam was taken in a 250 ml of clean beaker and 50ml of distilled water was added to it. Then it was boiled well for about 10 min. Then it is allowed to cool and filtered in a 100 ml volumetric flask and made up to 100 ml with distilled water. This preparation is used for the qualitative analysis of acidic/ basic radicals and biochemical constituents in it.

Preparation of extract:

5gm of Kukkil Chooranamis weighed accurately and placed in a 250ml clean beaker and 50ml of distilled water was added with it. Then it was boiled well for about 10 minutes. Then it was allowed to cool and filtered in a 100ml volumetric flask and made up to 100ml with distilled water.The bio-chemical analysis of Kukkil Chooranamwas done at Biochemistry lab, National Institute of siddha, Chennai-47.

Preliminary test forCopper, Sodium, Silicate and Carbonate:

- **Test for Silicate:**

a. A little (500mg) of the sample is shaken well with distilled water.

b. A little(500mg) of the sample is shaken well with con. HCl/Con. H_2So_4.

- **Action of Heat:** A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.
- **Action of Heat:** A small amount (500mg) of the sample is taken in a dry test tube and heated gently at first and then strong.
- **Flame Test:** A small amount (500mg) of the sample is made into a paste with con. HCl in a watch glass and introduced into non-luminous part of the Bunsen flame.
- **Ash Test:** A filter paper is soaked into a mixture of sample and dil. cobalt nitrate solution and introduced into the Bunsen flame and ignited.

Test For Acid Radicals

- **Test For Sulphate:**2ml of the above prepared extract was taken in a test tube and 2ml of 4% dil. ammonium oxalate solution was added.
- **Test For Chloride:**2ml of the above prepared extracts was added with 2ml of dil-HNO_3 until the effervescence ceases off. Then 2 ml of silver nitrate solution was added.
- **Test For Phosphate:** 2ml of the extract was treated with 2ml of con.HNo3 and 2ml of dil. ammonium molybdate solution.
- **Test For Carbonate:** 2ml of the extract was treated with 2ml dil. magnesium sulphate solution
- **Test For Nitrate:**1gm of the substance was heated with copper turning and concentrated H_2SO_4 and viewed the test tube vertically down.
- **Test For Sulphide:** 1gm of the substance was treated with 2ml of con. HCL
- **Test For Fluoride & Oxalate:** 2ml of extract was added with 2ml of dil. Acetic acid and 2ml dil.calcium chloride solution and heated**.**
- **Test For Nitrite:** 3drops of the extract was placed on a filter paper, on that-2 drops of dil.acetic acid and 2 drops of dil. Benzidine solution were placed.

Test For Basic Radicals

- **Test For Lead:** 2ml of the extract was added with 2ml of dil. potassium iodine solution.
- **Test For Copper:** One pinch (50mg) of substance was made into paste with con. HCl in a watch glass and introduced into the non-luminous part of the flame.
- **Test For Aluminium:** In the 2ml of extract dil. sodium hydroxide was added in 5 drops to excess.
- **Test For Iron:**

a.To the 2ml of extract add 2ml of dil. ammonium solution

b. To the 2ml of extract 2ml thiocyanate solution and 2ml of con HNo3 is added

- **Test For Zinc:** In 2ml of the extract dil.sodium hydroxide solution was added in 5 drops to excess and dil.ammonium chloride was added.
- **Test For Calcium:** 2ml of the extract was added with 2ml of 4% dil.ammonium oxalate solution

- **Test For Magnesium:** In 2ml of extract dil.sodium hydroxide solution was added in drops toexcess.
- **Test For Ammonium:**In 2ml of extract 1 ml of Nessler's reagent and excess of dil. sodium hydroxide solution were added.
- **Test For Potassium:**A pinch (25mg) of substance was treated with 2ml of dil. sodium nitrite solution and then treated with 2ml of dil. cobalt nitrate in 30% dil. glacial acetic acid.
- **Test For Sodium:** 2 pinches (50mg) of the substance was made into paste by using HCl and introduced into the blue flame of Bunsen burner.
- **Test For Mercury:** 2ml of the extract was treated with 2ml of dil. sodium hydroxide solution.
- **Test For Arsenic:** 2ml of the extract was treated with 2ml of dil. sodium hydroxide solution.

Other constituents

- **Test For Starch :** 2ml of extract was treated with weak dil. iodine solution
- **Test For Reducing Sugar:** 5ml of Benedict's qualitative solution was taken in a test tube and allowed to boil for 2 minutes and added 8 to 10 drops of the extract and again boil it for 2 minutes.
- **Test For The Alkaloids**:

a) 2ml of the extract is treated with 2ml of dil. potassium iodide solution.
b) 2ml of the extract is treated with 2ml of dil.picric acid.

- **Test For Tannic Acid:** 2ml of extract was treated with 2ml of dil. ferric chloride solution
- **Test For Unsaturated Compound:** In the 2ml of extract 2ml of dil. Potassium permanganate solution was added.
- **Test For Amino Acid:** 2 drops of the extract was placed on a filter paper and dried well, and then 20ml of Burette reagent was added in it.

TOXICITYSTUDIESOFKUKKIL CHOORANAM

To evaluate the safety profile of Kukkil chooranam short term and long term toxicity study carried out as followed. The principles of laboratory animal care were followed and the Institutional Animal Ethical Committee approved the use of animals and the study design. IAEC registered and approval number: (IAEC).(NIS/IAEC/III/06/29092016dated29.09.2016) for Short term toxicity study and Long term toxicity study

ExperimentalAnimals:

Species	:	Wistar albino Rats
Sex	:	Male and Female
Age/weight at start of test	:	6 weeks/140-160g b.wt
Acclimatization Period	:	7 days prior to dosing
Housing	:	Polypropylene cages with bedding with husk
Husbandry	:	12-h light/12-h dark cycle/ Room temperature 22°C±3°C and relative humidity30–70%
Feed and Water	:	Rodent pelleted feed RO purified water ad*libitum*
Identification	:	Animals will be kept in Polypropylene cages and numbered

Experimentation Details of Short term Toxicity Study:

Groups/Treatment regimen	:	Grouped by randomisation
Test Guideline	:	WHO
Length of exposure to test substance	:	1 day
No of Animals	:	5 Female+ 5 Male / group
Control group	:	Vehicle(honey)
Test groups	:	Kukkil Chooranam2000 mg/kg.b.wt

The wistar albino rats of both sex weighing 150-200g will be obtained from authorized animal breeders of animal laboratory inTANUVAS, Madavaram, Chennai

and stocked in animal house atNational Institute of Siddha, Chennai. Animals will be house in cage at 22°C±3°C andrelative humidity 30–70% and have free access to standard rat pellet diet (Sai Meera Foods Pvt. Ltd., Bangalore). The animals will be dosed with Kukkil chooranam by oral for one day and monitored for behavioural parameters for the first 4 hours after drug administration. Body weight of the animal will be monitored at weekly intervals. The animals that the die within this period will be subjected to necropsy. Remaining animals will be weighed and sacrificed under the injuction of Pentathal Sodium on the 15thday of the Study period.The toxicologicaleffectwereassessedonthe basisofmortality.

PreparationofTestDrugDoses:

Groups	No. of Rat
Group I: Vehicle control (honey)	10 (5M+5F)
Group II: test drug (KC)- 2000 mg/kg b.wt	10 (5M+5F)

***KC**- *Kukkilchooranam*

Route of administration

Oral route were selected because it is the normal route of clinical administration.

Administration of Dose

The animals were kept in fasting (only food was with held) for 12 hrs and weighed prior to dosing. Three animals were used for each step. A single dose of the solution (2000mg/kg) was consecutively administered by oral gavage using intubation cannula. Food was with held for another 4 hrs after dosing and administration of drug. As per the guideline the starting dose level was taken as 2000mg/kg body weight.

Observations:

Observations were made and recorded systematically and continuously observed after the substance administration as per the guidelines.

- ✓ ½ hour, 1 hour, 2 hour, 4 hour and upto 24 hours observation
- ✓ All rats will be observed twice daily on week days for 14 days
- ✓ Body weight per weekly one times
- ✓ Feed intake per day

Cage side observation

The animals were monitored for behavioral parameters like, Alertness, Aggressiveness, pilo erection,Grooming, Gripping,Touch Response, Motor Activity, Tremors,Convulsions, Muscle Spasm,Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea,Writhing, Respiration, Mortality

Necropsy:

Necropsy includes gross examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals, uterus, of all animals.

Experimentation Details of Long term Toxicity Study:

Experimental Animals:

Species	:	Wistar Albino Rats
Sex	:	Male and Female
Age/weight at start of test	:	6 weeks/140-160g b.wt
Acclimatization Period	:	7 days prior to dosing
Housing	:	Polypropylene cages with bedding with husk
Husbandry	:	12-h light/12-h dark cycle/ Room temperature 22°C±3°C and relative humidity 30–70%
Feed and Water	:	Rodent pelleted feed RO purified water ad *libitum*
Identification	:	Animals will be kept in polypropylene cages and numbered

Experimentation Details of Acute Toxicity Study:

Groups/Treatment regimen	:	Grouped by randomisation
Test Guideline	:	WHO
Length of exposure to test substance	:	90 days
No of Animals	:	10 Female+10 Male / group
Control group	:	Vehicle(honey)
Test groups	:	Kukkil Chooranam (Low dose, Mid dose, High dose)

The 80 Wistar albino rats of both sex selected randomly. The animals were divided into four groups. Each groups consist at 20 animals. First group treated as vehicle control and second, third and fourth groups were treated with Kukkil chooranam Low dose (180 mg), Mid dose (900 mg) and High dose (1800 mg) respectively. The animals were dosed with Kukkil chooranam by oral for 90 days and is monitored for behavioural parameters for the first 4 hours after drug administration. Body weight of the animal was be monitored at weekly intervals. The animals that die within this period was be subjected to necropsy. Remaining animals was be weighed and sacrificed under the injuction of Pentathal Sodium on the on the 91st day of the study. Blood will be collected from the anesthetized animals from Abdominal aorta. and the following investigations like Haematology, Biochemical analysis and Histopathology are done.

They above dose were fixed from the result of Short term toxicity study

Groups	No. of Rats
Group I: Vehicle control (honey)	20(10M+10F)
GroupII:Test drug (*KC*)- low dose (180mg/kg b.wt)	20(10M + 10F)
GroupIII: Test drug(*KC*) - Mid dose (900mg/kg.b.wt)	20(10M +10F)
GroupIV:Test drug(*KC*) High dose (1800 mg/kg b.wt)	20(10M +10F)

***KC-** Kukkil chooranam

Preparation and administration of dose:

*Kukkil Chooranam*was dissolved in honey to obtain concentrations of 1800mg/ml. It was administered to animals at the dose levels of 180mg/kg b.wt, 900mg/kg b.wtand1800mg/kg b.wt. The test substance solutions were freshly prepared every two days once for 90days. The control animals were administered with honey as vehicle. Administration was given by oral, once daily for 90 consecutive days.

Observations:

Experimental animals were kept under observation throughout the course of study For the following

- ✓ All rats will be observed twice daily on week days for 90 days
- ✓ Body weight per weekly one times
- ✓ Feed intake per day

Cage side observation

The animals were monitored for behavioral parameters like, Alertness, Aggressiveness, pilo erection, Grooming, Gripping, Touch Response, Motor Activity, Tremors, Convulsions, Muscle Spasm, Catatonia, Muscle relaxant, Hypnosis Analgesia, Lacrimation, Exophthalmos, Diarrhea, Writhing, Respiration, Mortality.

Gross necropsy:

Gross necropsy includes examinations of the external surface of the body, all orifices, cranial, thoracic and abdominal cavities and their contents. Brain, eye, lungs, heart, spleen, liver, kidneys, adrenals, uterus, of all animals.

Laboratory Investigations:

On the91st day,the animalswerefastedovernight,thenanesthetizedto collectblood samplesfromtheabdominalaorta intwotubes: onewith EDTA forhematologicalparameters,anotheronewithoutanyanticoagulantandwascentrifugedat 4000rpmat4°Cfor10minutestoobtaintheserumforbiochemicalparameters.

***HematologicalInvestigations*:**

Blood samples of control and experimental rats were analyzed for hemoglobin (Hb), total red blood corpuscles (RBC), white blood corpuscles (WBC) count, Mean corpuscular volume (MCV), Mean corpuscular hemoglobin(MCH) were calculated.

***Biochemical Investigations*:**

Serum samples of control and experimental rats were analysed for Bilirubin, Uric Acid, Creatinine, Triglyceride, Total Cholesterol, HDL, LDL, VLDL, using standard methods. Activities of glutamate oxalo acetate transaminase/Aspartate amino transferase (GOT/AST) and glutamate pyruvate transaminase/ Alanine amino transferase (GPT/ALT) were estimated as per the colorimetric procedure.

Necropsy:

All the animals were sacrificed on the 91st day. Necropsy of all animals was carried out and the weights of the organs including liver, kidneys, spleen, brain, heart, lungs and stomach were recorded.

Histopathology:

The organs included liver, kidneys, spleen, brain, heart, lungs and stomach of the animals were preserved, and they were subjected to histopathological examination.

Histopathological investigation of the vital organs was done. The organ pieces(35µm thick) of the three different (low, mid, high) dose level was preserved and was fixed in 10% formalin for 24 hand was hed in running water. Samples were dehydrated in an auto technic on and then cleared in benzene to remove absolute alcohol. Embedding was done bypassing the cleared samples through three cups containing molten paraffin at 50°C and then in a cubical block of paraffin made by the "L" molds. It was followed by micro to me and the slides were stained with Haematoxylin-eosin.

Statistical analysis:

Findings such as body weight changes, food consumption, water intake, hematology and biochemical analysis were subjected to One-way ANOVADunnet's test using a computer software program followed by D *Graph Pad Instat-3*.

CLINICAL STUDY:

STUDY DESIGN:

STUDY TYPE	:	An open clinical trail
STUDY PLACE	:	OPD and IPD of Ayothidoss Pandithar Hospital, National Institute of Siddha, Tambaram Sanatorium, Chennai - 47.
STUDY PERIOD	:	18 Months
SAMPLE SIZE	:	40 patients (Both IPD & OPD)

SUBJECT SELECTION:

Patients reporting with symptoms of inclusion criteria will be subjected to screening test and documentation.

INCLUSION CRITERIA

- Age : 20-60 years
- Sex : Both male and female
- Presence of ulcers with varicose veins
- With or without Pain, Itching, Edema, Fibrinous exudates in the lesions
- Hyper pigmentation
- Eczema around the ulcer
- Willing to give specimen of blood for the investigation.
- Permit to take photograph.
- Willing to participate in trial and signing consent by fulfilling the condition of Proforma.

EXCLUSION CRITERIA

- H/o of Diabetes Mellitus.
- H/o of Hansen's disease.
- H/o of Diabetic ulcer
- H/o of Gangrene
- H/o of Tuberculosis ulcer
- H/o of any other systemic illness.

WITHDRAWAL CRITERIA

- Intolerance to the drug and development of any serious adverse effect during drug trial.
- Poor patient compliance & defaulters
- Patient unwilling to continue the course of clinical Study.
- Occurrence of any other systemic illness

TESTS AND ASSESMENTS:

1. Clinical assessment
2. Siddha system assessment
3. Routine investigations

1. **CLINICAL ASSESMENT:**

- Presence of ulcers with varicose veins
- With or without Pain, Itching, Edema, Fibrinous exudates in the lesions
- Hyper pigmentation
- Eczema around the ulcer

1. INVESTIGATIONS BASED ON SIDDHA SYSTEM:

1. Naadi
2. Sparisam
3. Naa
4. Niram
5. Mozhi
6. Vizhi
7. Malam
8. Moothiram ● Neerkkuri: ● Neikkuri:

1. INVESTIGATION:

BLOOD

- Hb
- Total WBC Count
- DC
  - Polymorphs
  - Lymphocytes
  - Eosinophils
  - Monocytes
  - Basophils
- Total RBC count
- ESR - ½ Hr: 1 Hr:
- Blood sugar Fasting: PP:
- Serum cholesterol

URINE

- Albumin
- Sugar(F) (PP)
- Deposits

RENAL FUNCTION TESTS

Blood Urea

Serum Creatinine

Uric acid

LIVER FUNCTION TESTS

Serum total bilirubin

Direct bilirubin

Indirect bilirubin

Serum Alkaline phosphatases

SGOT

SGPT

DATA COLLECTION:

Required information were collected from each patient by using the following forms

FORMS:

FORM I	Screening and selection Proforma
FORM II	Clinical assessment Proforma
FORM III	Laboratory investigation Proforma
FORM IV	Patient information sheet
FORM V	Consent form
FORM VI	Withdrawal form/Pharmacovigilance
FORM VII	Dietary Advice form

STUDY ENROLLMENT:

- Patients reporting at the OPD with clinical feature of chronic ulcer, oedema, skin hyperpigmentation, fibrinous exudate, itching and eczema around the ulcer were chosen for enrolment based on the inclusion and exclusion criteria.

- The enrolled patients were informed about the study, trial drug, possible outcomes and the objectives of the study in the language and terms understandable to them and getting consent in the Informed Consent form (Form VI).
- Complete clinical history, complaints and duration, examination findings-- all would be recorded in the prescribed Performa's.
- Screening Form- I will be filled up, Form –II and Form –III were used for recording the patients, history, clinical examination of symptoms and signs and laboratory investigations respectively. If there is any abnormal laboratory reports obtained then excluded from this study. Patients would be advised to take the trial drug and appropriate dietary advice (Form VII) would be given according to the patients, perfect understanding.

CONDUCT OF THE STUDY:

The day before the treatment Purgation were given with *Agasthiyar Kuzhambu* 200mg in the early morning in empty stomach with Sangankuppi juice for balancing the deranged humours. Then the trial drugs "*KUKKIL CHOORANAM*" (Internal) an "*THUVARA ENNAI*" (External) were given for 48 days.

OPD patients are requested to visit the hospital once in 7 days. In each and every visit clinical assessment and prognosis were recorded in the presence of faculty members. For IPD patients the clinical assessment and prognosis were recorded daily.

Laboratory investigations were done before and after the trial. For IPD patients, who are not in a position to stay in the hospital for a long time, are advised to attend the OPD for further follow-up. At the end of the trial, the patients are advised to visit the OPD for follow-up for any recurrence. Defaulters were withdrawn from the study with fresh case being inducted.

ADVERSE/SERIOUS EFFECTS MANAGEMENT:

In this study, no adverse reactions were observed during the course of treatment.

DATA ANALYSIS:

After enrolling the patients in the study, a separate file for each patient was maintained and all forms was kept in the file. Study No. and patient's No. was entered

on the top of the file for easy identification. Whenever the patients visit OPD during the study period, necessary entries was made at the assessment forms.

The screening forms were filled separately.

All forms were further scrutinized by Senior Research Officer (Statistics) for logical errors and incompleteness of data to avoid any bias. No modification in the results is permitted for unbiased reports.

OUTCOME:

Improvement assessed by following assessment:

1. The Outcome of the treatment will be observed by Venous clinical severity score (VCSS) before and after treatment.

VENOUS CLINICAL SEVERITY SCORE

ATTRIBUTE	ABSENT=0	MILD=1	MODERATE=2	SEVERE=3
PAIN	None	Occasional, not Restricting activity or Requiring pain Medication	Daily moderate activity Limitation; occasional Pain medication	Daily, severe limiting Activities or requiring Regular use of pain Medications
VARICOSE VEINS	None	Few scattered	Multiple; great Saphenous Veins, confined to calf And thigh	Extensive; thigh and calf or Great and small saphenous Distribution
VENOUS EDEMA	None	Evening ankle swelling Only	Afternoon swelling, Above ankle	Morning swelling above Ankle and requiring Activity change, elevation
SKIN PIGMENTATION	None	Diffuse, but limited in Area and old (brown)	Diffuse over most of Gaiter distribution (lower Third) or recent Pigmentation (purple)	Wider distribution (above Lower third) plus recent Pigmentation
INFLAMMATION	None	Mild cellulitis, limited To marginal area Around ulcer	Moderate cellulitis, Involves most of (lower third)	Severe cellulitis (lower Third and above) Or significant

INDURATION	None	Focal, circummalleolar	Medial or lateral, less Than lower third of leg	Entire lower third of leg or more
NUMBER OF ACTIVE ULCERS	0	1	2	>2
ACTIVE ULCER DURATION	None	<3 months	>3 months, <1year	Not healed>1 year
ACTIVE ULCER DIAMETER	None	<2	2-6	>6
COMPRESSION THERAPY	Not used or Patient not Compliant	Intermittant use of Stockings	Wears elastic stocking Most days	Full compliance, Stockings + elevation

OUTCOME:

- **GOOD –** Complete healing of ulcer and 75-100% reduction of VCSS Score
- **MODERATE –** Partial healing of ulcer and 50-75% reduction in VCSS Score
- **MILD –** Slight reduction of ulcer and 25-50% reduction in VCSS Score
- **POOR –** No reduction of ulcer and 0-25% VCSS Score

OBSERVATION AND RESULTS

PRECLINICAL STUDY

QUALITATIVE ANALYSIS

PHYSICO-CHEMICAL ANALYSIS

Table-1: Colour, nature of Kukkil Chooranam

S.no	Parameters	Results	Method of Testing
1.	Colour	Yellowish green	By visual
2.	Odour	Odour(Omam Smell)	Olfactory examination
3.	Solublity	• Soluble in honey • Insoluble in water	Qualitative
4.	Nature	Powter	By visual

Table-2: Test for Basic radicals

S.no	Procedures	Kukkil Chooranam
1.	Test for Ammonium	-
2.	Test for Sodium	-
3.	Test for Magnesium	-
4.	Test for Aluminium	-
5.	Test for Potassium	+
6.	Test for Calcium	+
7.	Test for Ferrous iron	+
8.	Test for Copper	-
9.	Test for Zinc	-
10.	Test for Arsenic	-
11.	Test for Mercury	-
12.	Test for Lead	-

Inference

Bio-chemical analysis for basic radicals reveals that Kukil Chooranam contains Potassium, Calcium and Iron.

Table-3: Test for Acidic radicals

S.no	**Procedures**	Kukkil Chooranam
1.	Test for Sulphate	-
2.	Test for Chloride	+
3.	Test for Phosphate	+
4.	Test for Flouride&Oxalate	-
5.	Test for Nitrate	_

Table-4: Test for Acidic radicals

S.no	**Procedures**	Kukkil Chooranam
1.	Test for Starch	+
2.	Test for Reducing sugar	_
3.	Test for Alkaloids	+
4.	Test for Amino acids	_
5.	Test for Tannic acids	+
6.	Test for type of compounds	No Change

Inference

Bio-chemical analysis for acid radicals reveals that Kukil Chooranam contains Chloride, Starch, Alkaloids, Tannic acids

Toxicity study Results of Kukkil Chooranam

Table: 5 Dose finding experiment and its behavioural Signs of Toxicity

No	Dose Mg/kg	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
1.	Control	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-
2.	2000	+	-	-	+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-

1.Aletness 2.Aggressiveness 3.pilo erection 4.Grooming 5.Gripping 6.Touch Response 7. Motor Activity 8. Tremors 9.Convulsions 10.Muscle Spasm 11.Catatonia 12.Muscle relaxant 13.Hypnosis 14.Analgesia 15.Lacrimation 16.Exophthalmos 17.Diarrhoea 18.Writhing 19. Respiration 20.Mortality

+ Presence of Activity

- Absence of Activity

All the data were summarized in the form of table revealed no abnormal signs and behavioural changes in rats at the dose of 2000 mg/kg body weight administered orally

Short term Toxicity study

In short term toxicity study, the test drug atKukkil Chooranam for single dose(2000mg/kg b.wt) was administered.

There was no mortality or signs of toxicity observed after dosing Kukkil Chooranam 2000mg/kg body weight during the study period of 14 days. This indicate that the LD50 of Kukkil Chooranam is more then 2000mg/kg b.wt.

There was no changes in skin and fur, eyes and mucous membranes of all animals. The eating ,drinking habit, sleep pattern, locomotion were normal in all animals and no changes in body weight as compared to control group.

At the end of the 14 th day necropsy was done and there was no abnormality seen in test groups as compared to control group during the examination.

Long term Toxicity study

Table 6:Effect of Kukkil Chooranam on Biochemical parameters

Dose (mg/kg)	Control	LD	MD	HD
Total cholesterol(mg/dl)	111.26±1.16	148.9±22.3	151.95±19.8	148.2±20.8
HDL(mg/dl)	60.5±4.08	69.1±12.8	63.16±5.40	65±10.8
LDL(mg/dl)	31.16±5.03	60±20.8	60.16±13.6	63±12.39
VLDL(mg/dl)	16.43±2.72	19.8±6.2	23.26±5.51	17.95±6.24
Triglycerides(mg/dl)	49.66±2.33	42.6±16.1	42.08±10.18	46.41±9.1

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:1

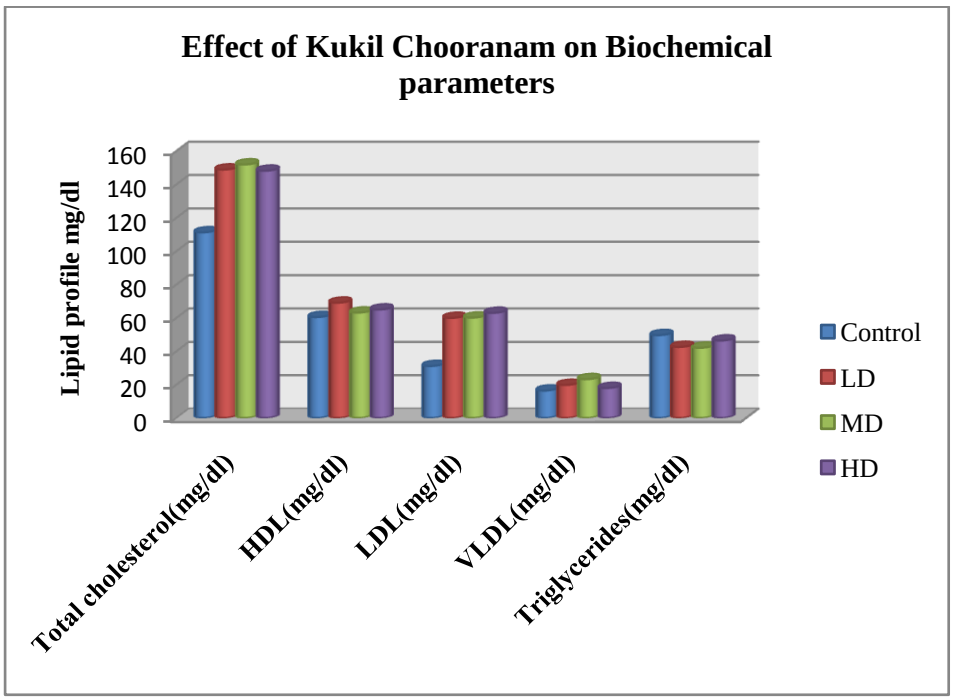


Table 7:Food (g/day) intake of albino rats exposed to Kukkil Chooranam

Dose (mg/kg/day)	Control	LD	MD	HD
1st day	5.54±0.21	6.11±0.21	5.59±0.25	6.2±0.15
15 th day	6.3±0.18	6.4±0.21	6.7±0.27	7.27±0.27
30 th day	6.7±0.27	7.07±0.17	6.65±0.18	7.45±0.24
45 th day	7.07±0.17	7.08±0.18	7.07±0.17	7.45±0.25
60 th day	7.07±0.17	7.27±0.27	7.37±0.24	7.45±0.25
75 th day	7.27±0.27	7.37±0.24	7.60±0.28	7.63±0.25
90 th day	7.60±0.28	7.63±0.25	7.95±0.11	7.75±0.13

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:2

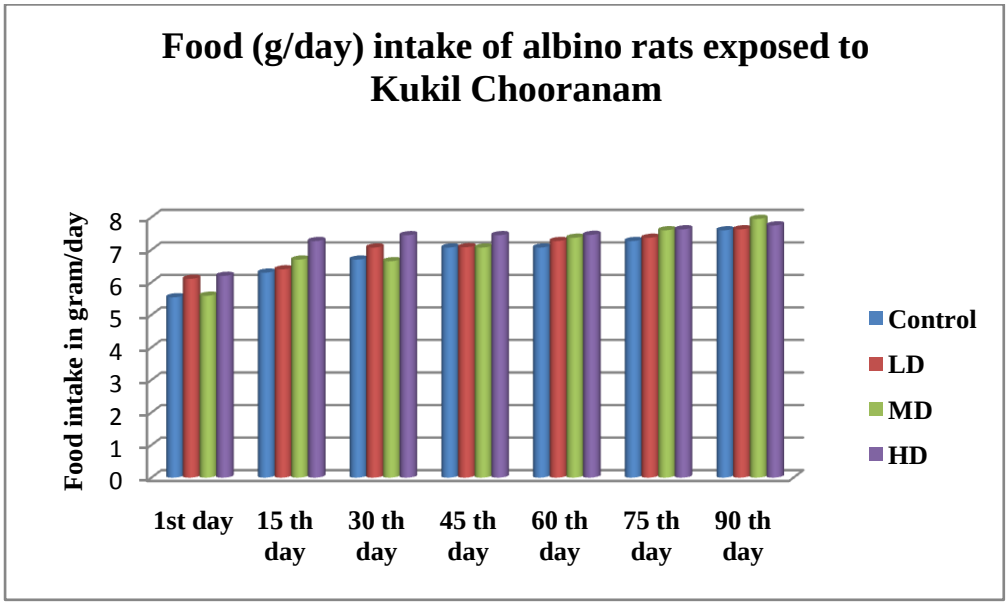


Table 8:Water (ml/day) intake of albino rats exposed to Kukil Chooranam

Dose (mg/kg/day)	Control	LD	MD	HD
1st day (ml/rat)	9.15±0.13	8.13±0.12	9.15±0.12	9.20±0.15
15 th day (ml/rat)	9.52±0.21	8.13±0.12	8.13±0.12	8.13±0.12
30 th day (ml/rat)	8.13±0.12	8.13±0.12	9.52±0.21	8.13±0.12
45 th day (ml/rat)	9.96±0.11	9.25±0.17	9.15±0.12	8.13±0.12
60 th day (ml/rat)	9.96±0.11	9.52±0.21	9.96±0.11	9.52±0.21
75 th day (ml/rat)	9.96±0.11	9.96±0.11	10.30±0.13	9.96±0.11
90 th day (ml/rat)	9.96±0.11	10.30±0.13	9.96±0.11	9.96±0.11

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:3

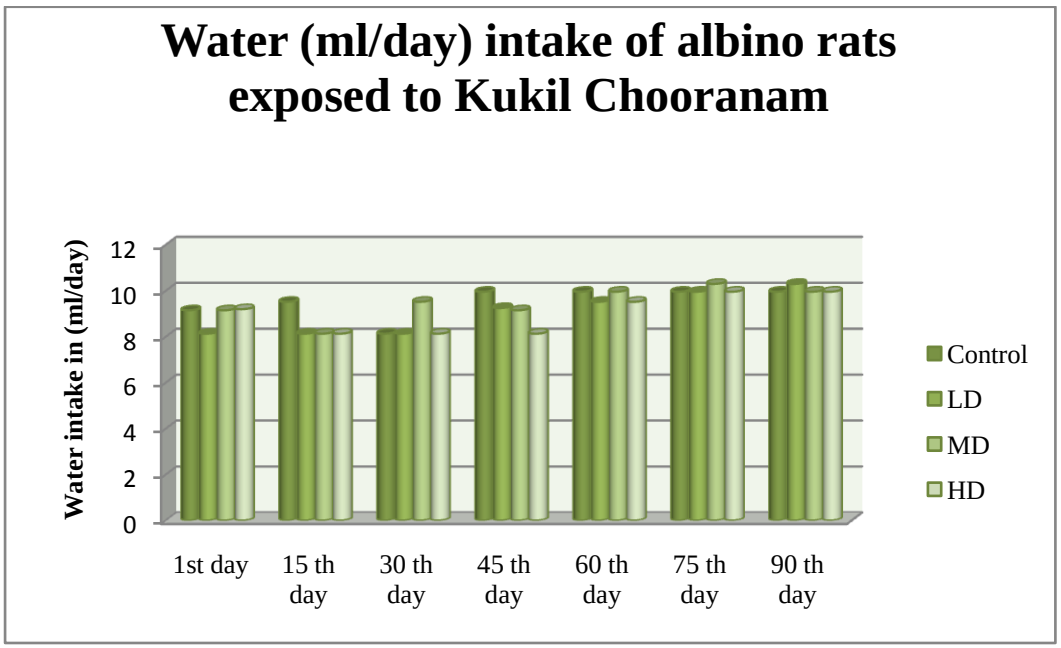


Table:9Body weight (g) changes of albino rats (female) exposed to Kukil Chooranam

Dose (mg/kg/day)	Control	LD	MD	HD
1st day	134.16±4.21	138.12±3.50	140.2±2.13	138.14±2.46
15 th day	164.16±4.21	158.45±2.16	162.36±5.07	157.25±1.67
30 th day	190.83±6.14	189.16±6.23	192.12±4.21	189.25±5.26
45 th day	209.16±5.07	206±4.21	210.2±6.30	207±3.16
60 th day	235.83±4.21	237.38±6.14	240.24±6.14	239.68±4.21
75 th day	270.83±6.30	272.5±5.02	278.8±2.36	276.26±6.24
90 th day	315.5±6.44	318.24±6.12	320.6±5.07	318.28±1.36

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:4

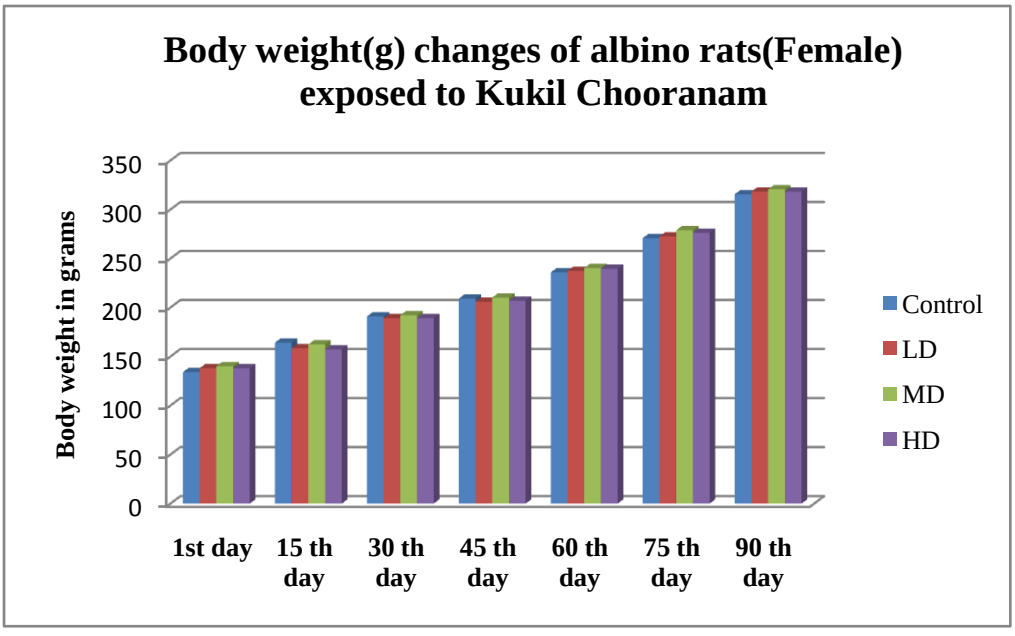


Table:10 Body weight (g) changes of albino rats (male) exposed to Kukil Chooranam

Dose (mg/kg/day)	Control	LD	MD	HD
1st day	139.33±4.13	142.24±4.12	152.16±2.45	148.16±6.27
15 th day	173±5.79	174.12±5.26	178.16±5.79	176±5.12
30 th day	203±5.79	204.16±4.23	202.18±9.12	206.33±2.4
45 th day	236.16±9.24	239±9.24	239.23±8.28	240.25±9.24
60 th day	288.66±9.24	292.25±6.23	297.26±5.20	296.67±2.67
75 th day	319.5±8.50	320.1±9.28	326.5±4.13	324.13±4.12
90 th day	359.5±9.71	352.18±6.58	348.16±7.02	347.4±8.50

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:5

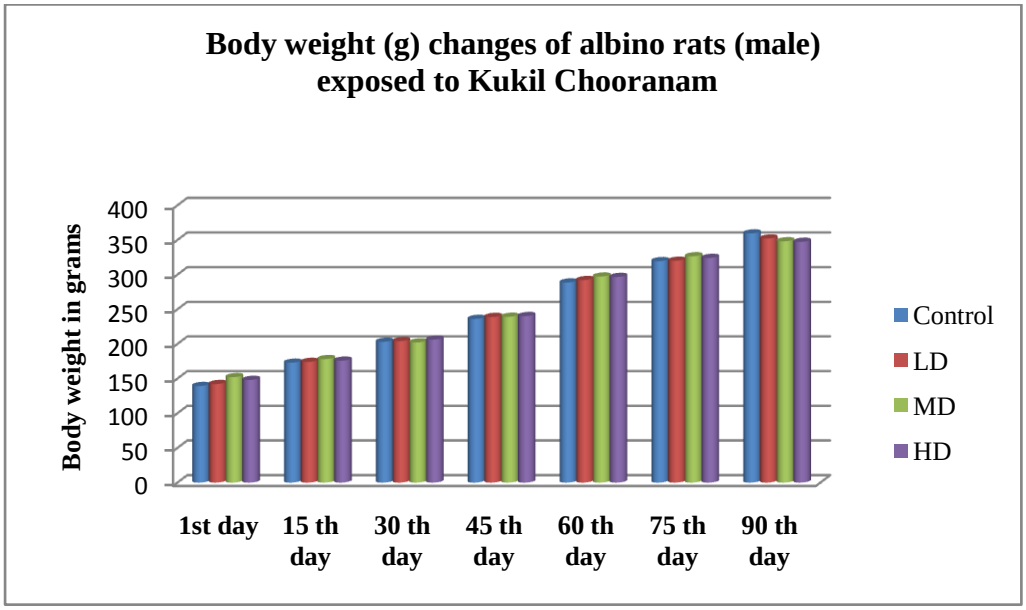


Table:11Effect of Kukil Chooranam on Haematological Parameters

Parameter	Control	LD	MD	HD
RBC(×10^{6}µl)	4.08±0.09	6.57±1.17	6.51±1.15	5.98±0.4
WBC(×10^{3}µl)	8.93±0.48	10.01±2.7	9.91±2.1	9.84±1.7
PLT(×10^{3}µl)	792.8±93.33	819.16±134.5	710.41±73.4	705.75±123.08
HGB(g/dl)	12.5±0.74	13.27±1.4	12.95±2.02	13.6±1.5
Neutrophils 10^3/mm^3	2.01±0.47	2.78±0.71	2.65±0.84	2.30±0.67
Lymphocyte(%)	76.4±1.52	78.2±9.88	72.59±11.1	74.4±10.2
Monocyte(%)	3.18±0.11	2.69±0.61	3.41±1.09	3.6±0.95
Eosinophils(%)	1.3±0.15	1.44±0.21	1.36±0.23	1.42±0.18
Basophils(%)	0.66±0.51	0.25±0.45	0.25±0.62	0.5±0.52
MCH(pg)	20.95±1.0	20.2±1.96	18.4±3.1	19.10±2.7
MCV(fl)	62.06±2.65	61.39±7.7	60.55±7.22	62.9±6.7

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:6

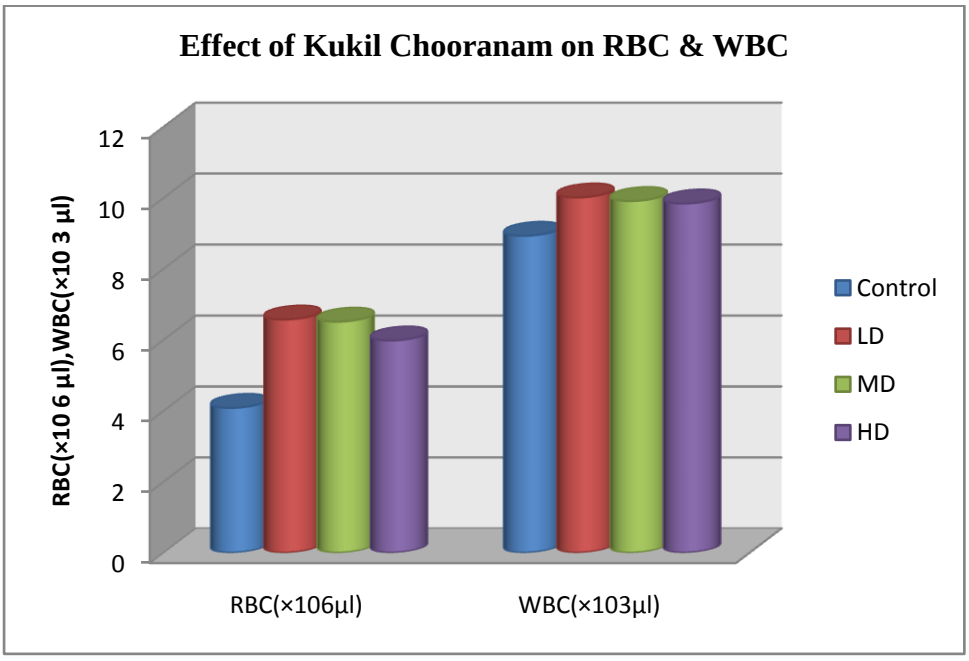


Figure:7

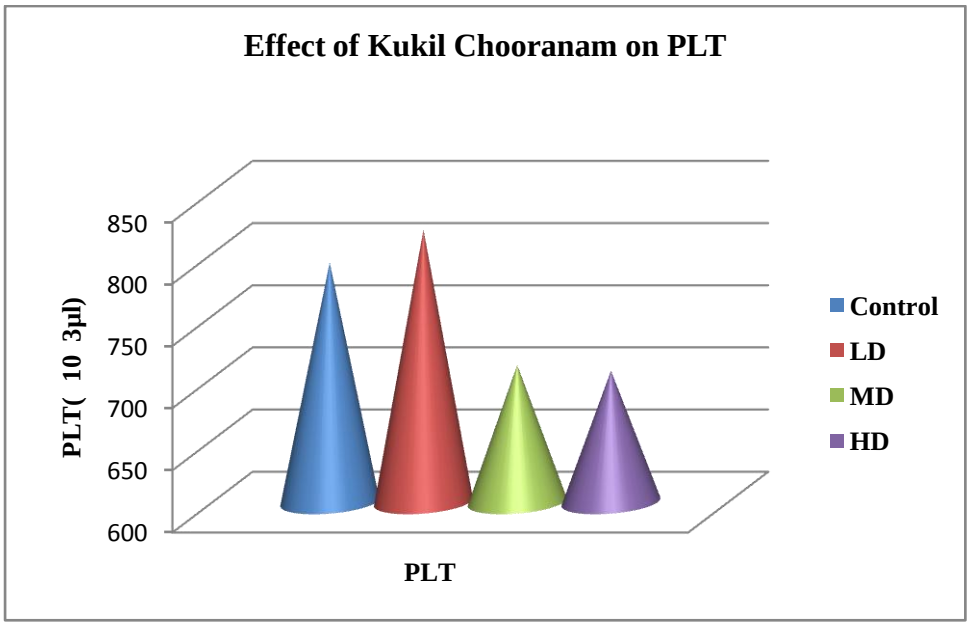


Figure:8

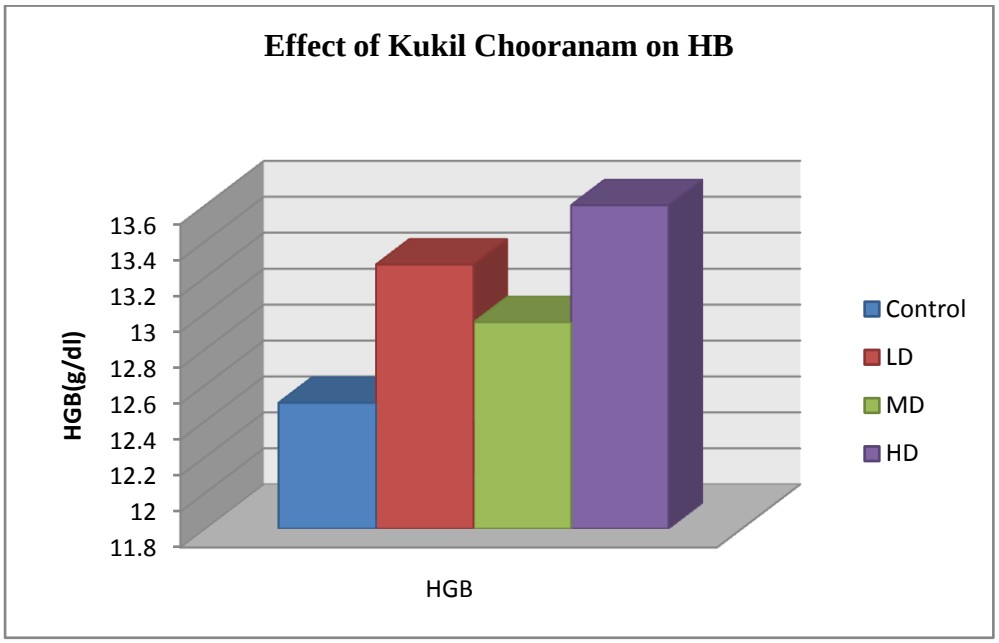


Figure:9

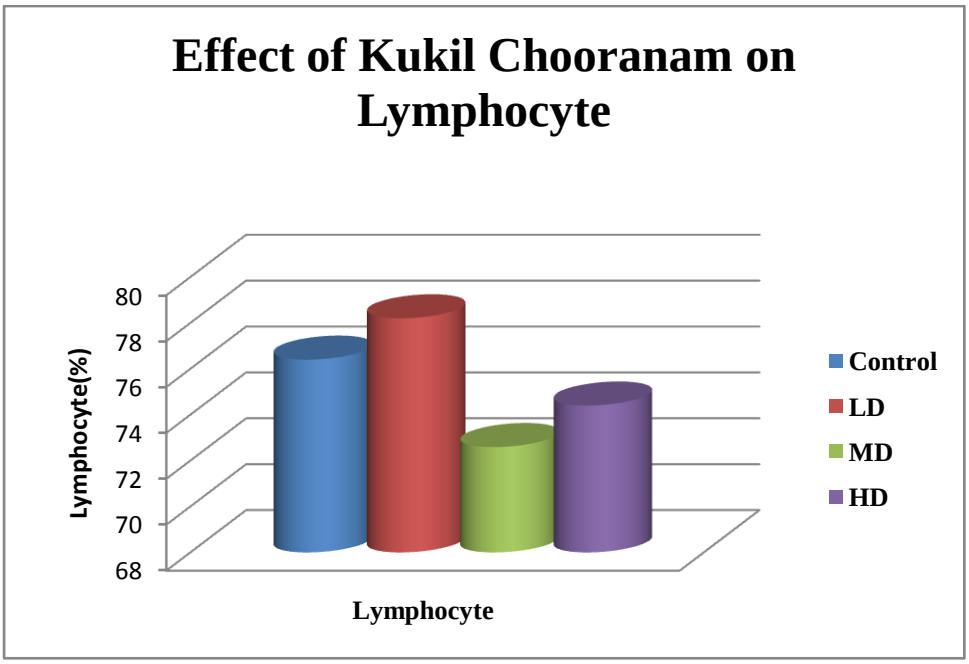


Figure:10

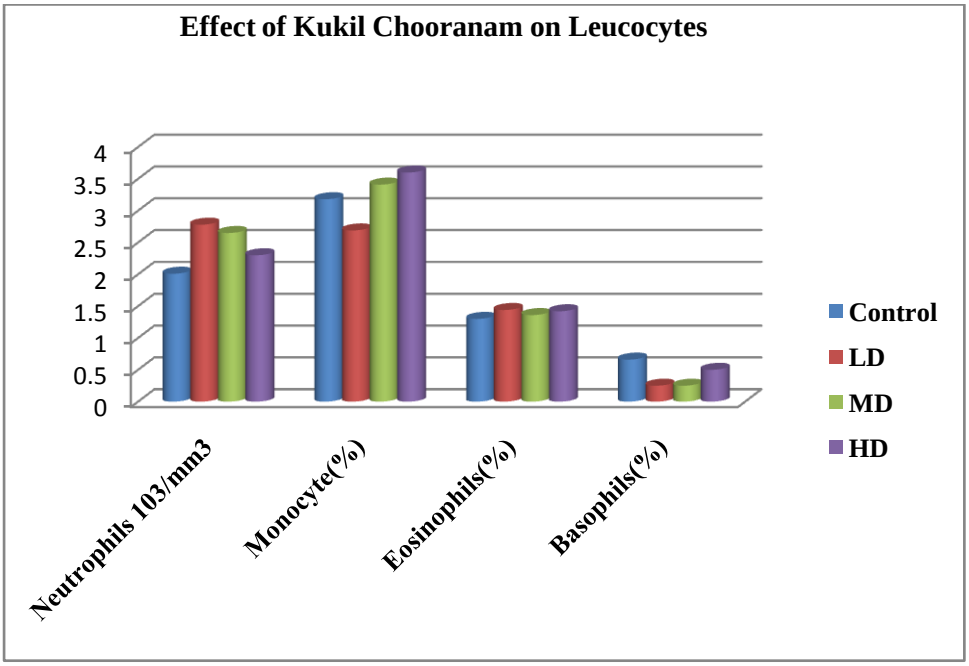


Figure:11

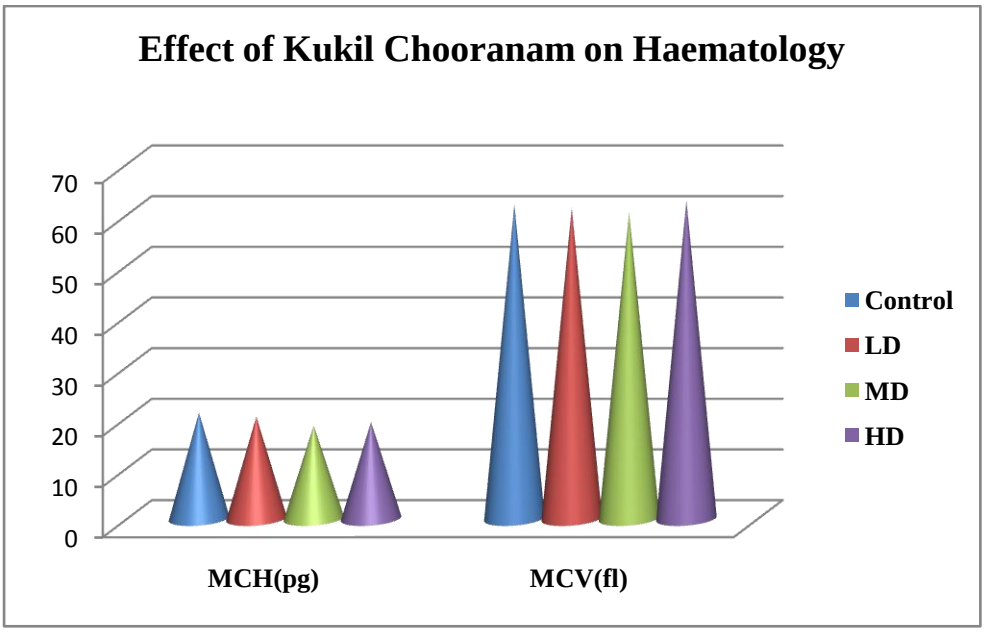


Table12 :Effect of Kukil Chooranamon Renal Parameters

Dose(mg/kg)	Control	LD	MD	HD
BUN(mg/dl)	15.91±2.2	15.37±2.7	14.4±3.09	17.14±2.4
Creatinine(mg/dl)	0.86±0.12	0.63±0.18	0.72±0.18	0.72±0.17

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:12

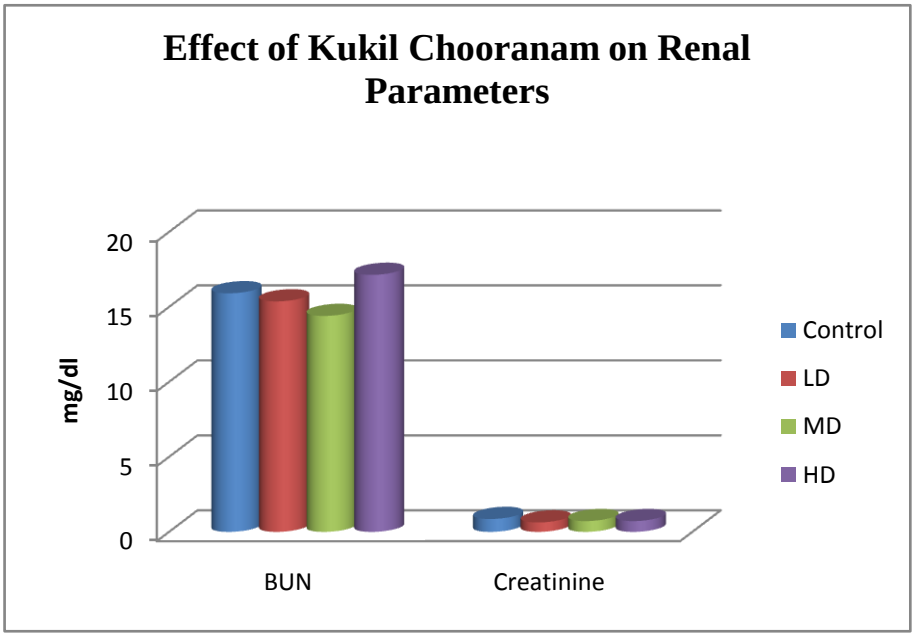


Table :13 Effect of Kukil Chooranamon Hepatic Parameters

Dose(mg/kg)	Control	LD	MD	HD
Total Bilirubin(mg/dl)	0.48±0.15	0.34±0.17	0.35±0.16	0.32±0.14
SGOT(U/L)	101±14.8	146.25±32.5	131.9±32.1	116.3±40.8
SGPT(U/L)	29.8±2.7	36.58±13.1	40.08±15.03	36±10.8

Values are mean± S.D. (Dunnett's test).*P<0.05,**P<0.01,N=12

Figure:13

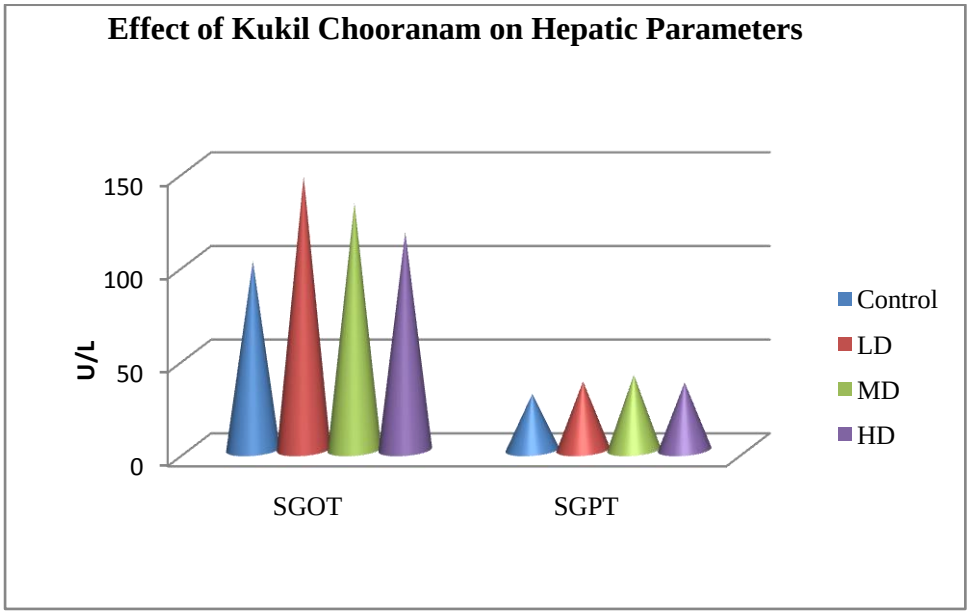
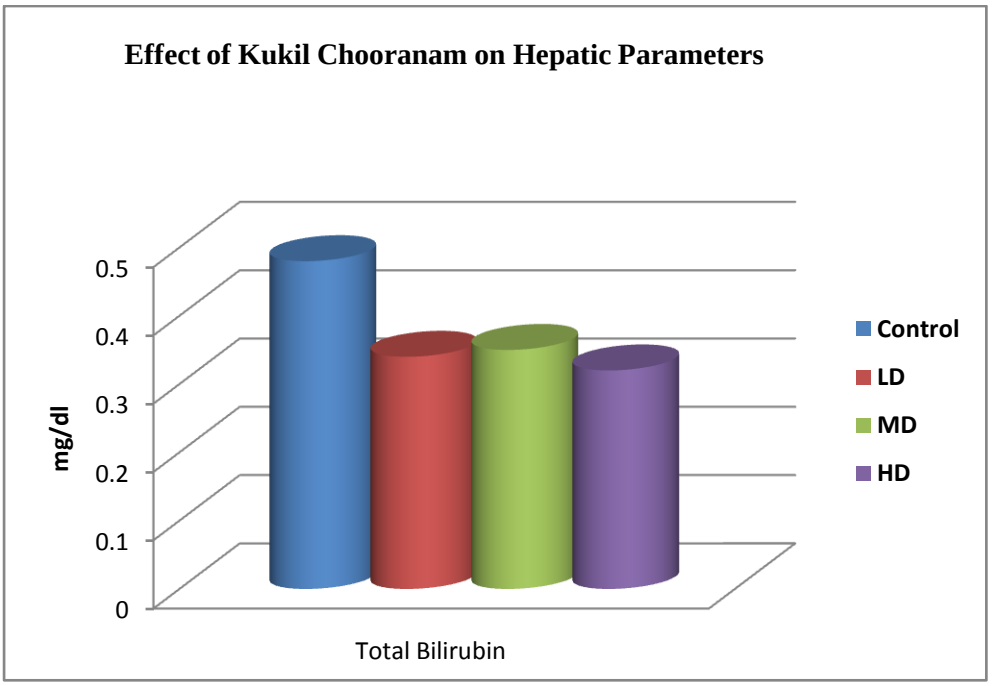


Figure:14


Effect of Kukil Chooranam on Hepatic Parameters
mg/dl
0.5
0.4
0.3
0.2
0.1
0
Total Bilirubin
Control
LD
MD
HD

Long term toxicity Study

Histopathology of Heart -Control

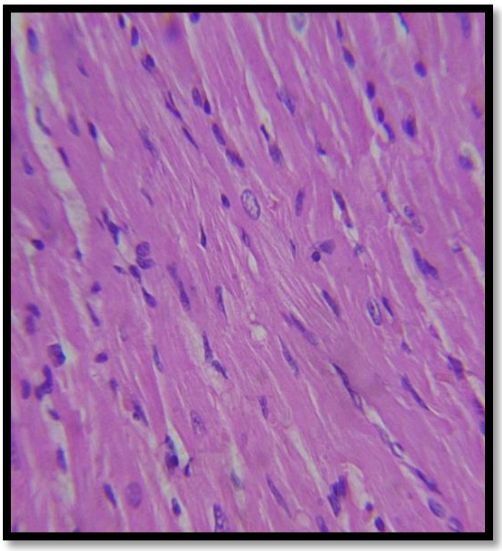


Plate a. Control

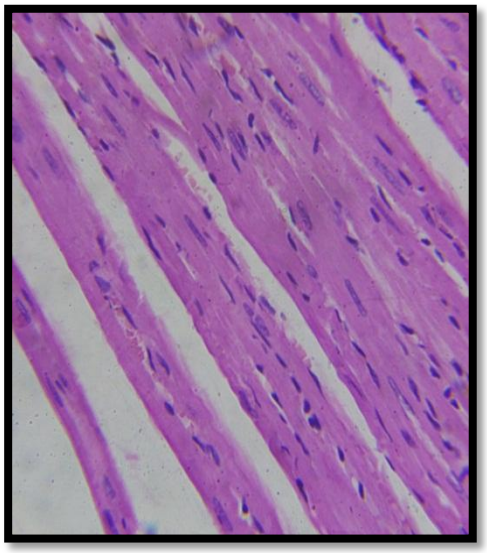


Plate b. Low dose group

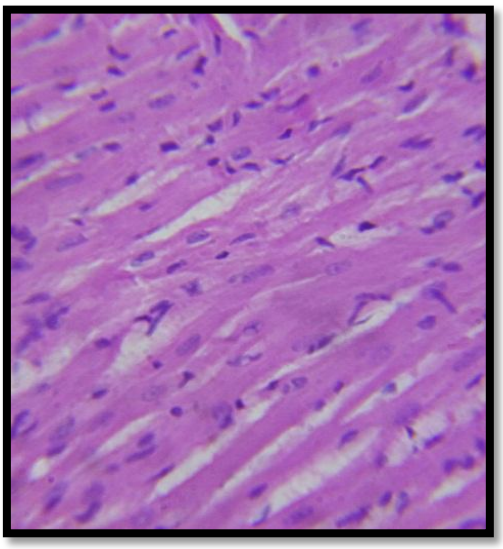


Plate c. Mid dose group

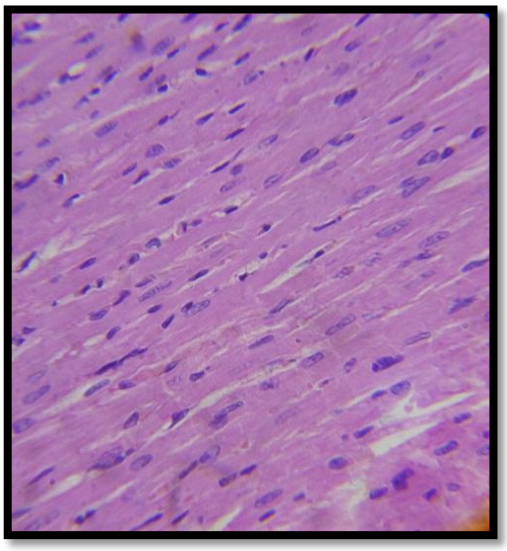


Plate d. High dose group

Plate a

- Nucleus appears prominent with regular arrangement of fibres. No evidence of pyknotic nucleus.
- No evidence of collagen deposition in myocardium.

Plate b

- Normal network of myocardial fibers were observed
- No evidence of atherosclerosis and thrombosis

Plate c

- Nuclei of cardiomyocytes appears regular size and shape
- Arrangement of cardiac myofibres was normal

Plate d

- Cardiac fibres appears normal with regular striations

Long term toxicity Study

Histopathology of Lungs

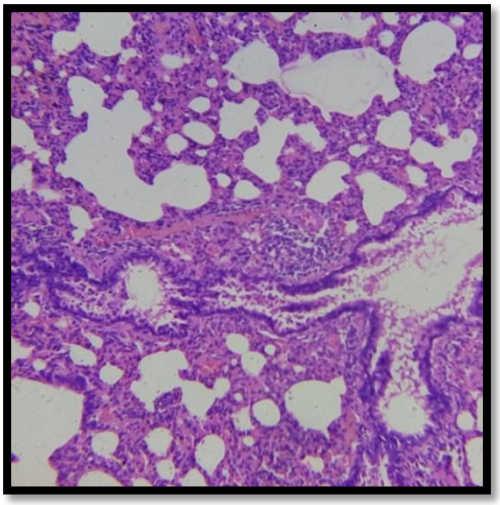


Plate a. Control

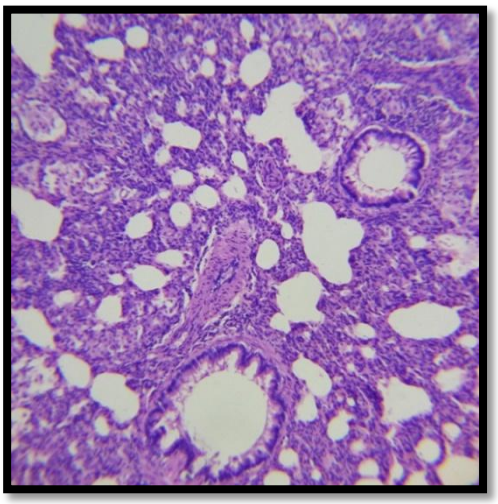


Plate b. Low dose group

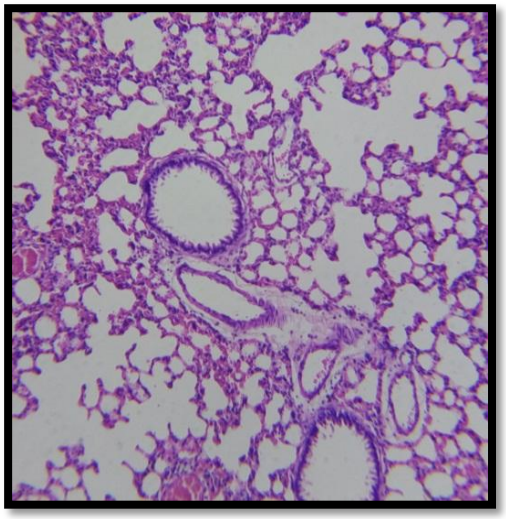


Plate c. Mid dose group

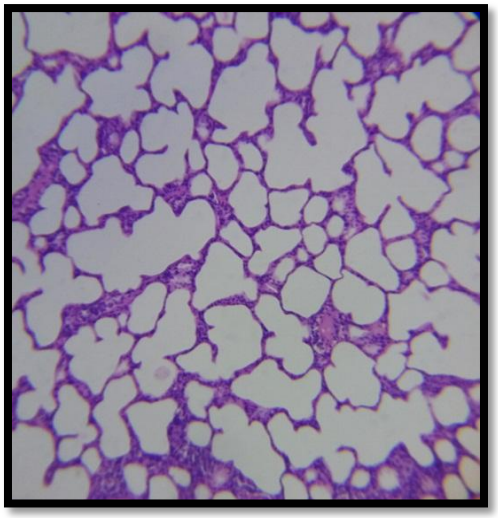


Plate d. High dose group

Plate a

- Lung parenchyma appears normal with regular arrangement of alveoli and alveolar sac with no signs of lymphocyte infiltration and pulmonary fibrosis
- No evidence of lymphocyte aggregation in deep airway layers

Plate b

- Normal lung parenchyma with regular airway histology was observed
- No evidence of perivascular cuffing

Plate c

- No evidence of lymphocyte proliferation
- Appearance of vascular sheath and perivascular regions are normal

Plate d

- No signs of airway secretion and bronchial secretion
- Bronchial blood vessels and connective tissue appears normal with no signs of pulmonary oedema

Long term toxicity Study

Histopathology of Liver

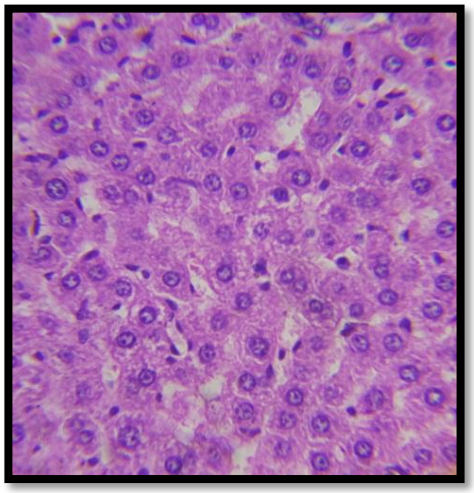


Plate a. Control

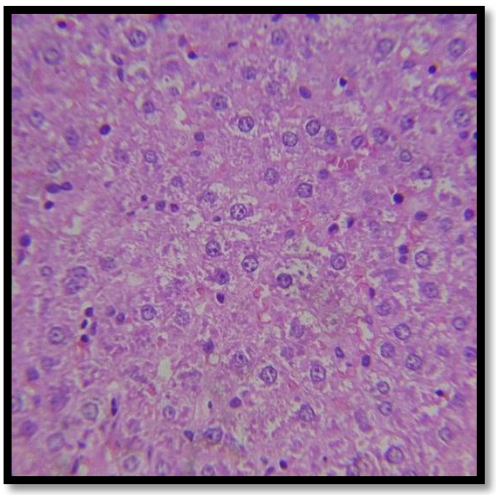


Plate b. Low dose group

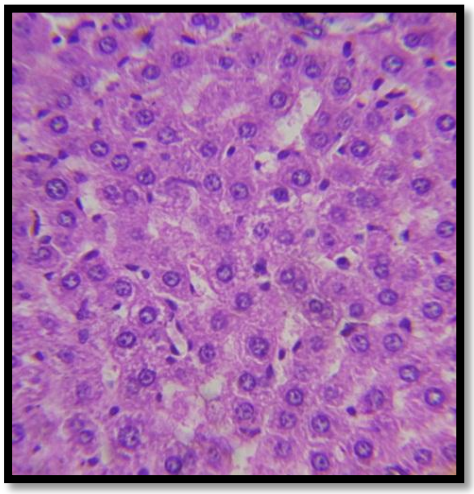


Plate c. Mid dose group

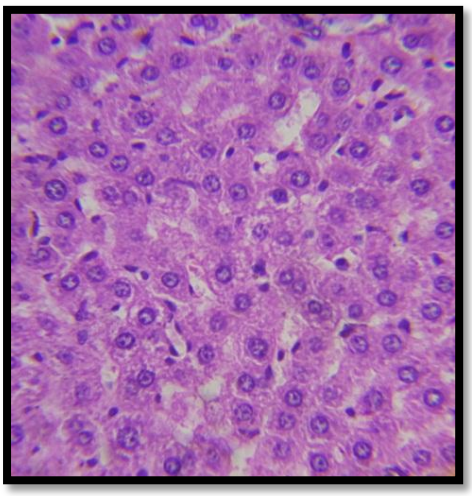


Plate d. High dose group

Plate a

- Hepatocytic cytoplasm appears normal. The centrilobular hepatocytes appears normal with stained cytoplasm
- No evidence of mesenchymal reaction on to the hepatic parenchyma.

Plate b

- Numerous hepatocytes appears with shrunken nucleus
- No signs of nodular degeneration and cirrhosis.
- No evidence of collagen (fibrosis)

Plate c

- kupffer cells were Normal
- No evidence of collagen (fibrosis)

Plate d

- Hepatocytic cytoplasm appears normal. The centrilobular hepatocytes appears normal with stained cytoplasm
- No evidence of mesenchymal reaction on to the hepatic parenchyma.

Long term toxicity Study

Histopathology of Stomach

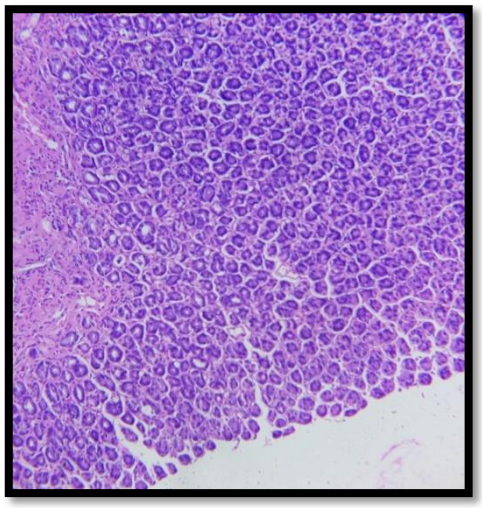


Plate a. Control

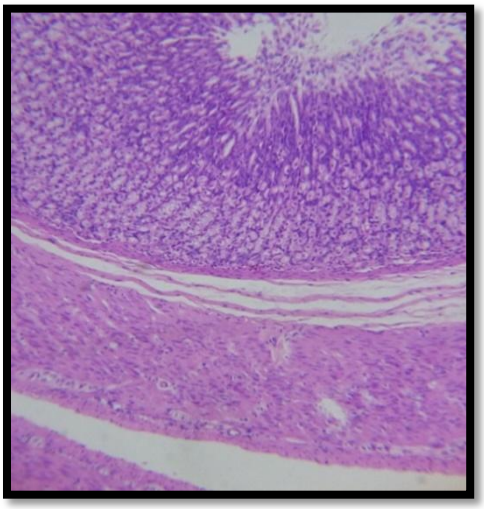


Plate b. Low dose group

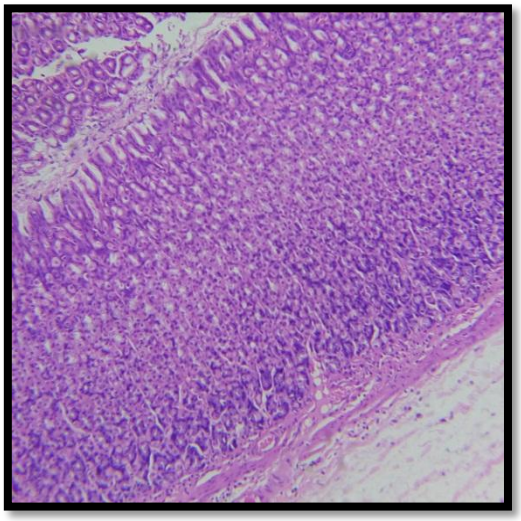


Plate c. Mid dose group

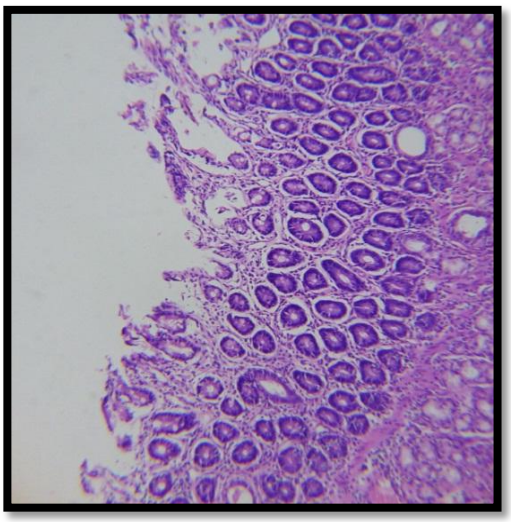


Plate d. High dose group

Plate a

- Mucosal wall appears normal with regular arrangement of connective tissue
- Histology of gastric wall composed of normal mucosa, muscularismucosa, submucosa, muscularispropiria and adventitia

Plate b

- Intracytoplasmic zone of mucosa appears normal
- Histology of gastric wall composed of normal mucosa, muscularismucosa, submucosa, muscularispropiria and adventitia.

Plate c

- Light microscopic observation stomach reveals normal histology of gastric wall composed of normal mucosa, muscularismucosa, submucosa, muscularispropiria and adventitia. No signs of ulceration were observed

Plate d

- Appearance of glandular lumen was normal. Lamina propria appears normal with no evidence of infiltration and inflammation.

Long term toxicity Study

Histopathology of Spleen

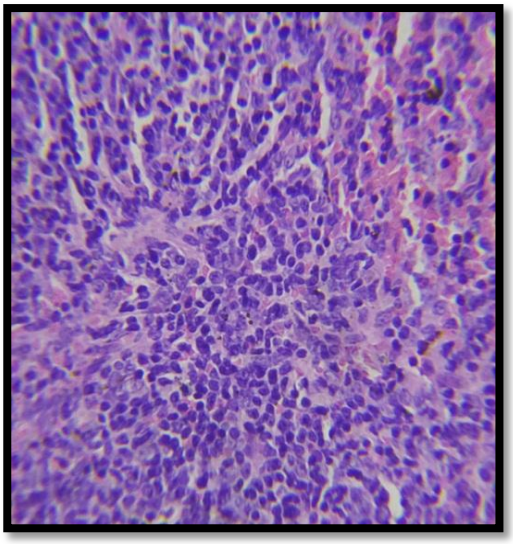


Plate a.Control

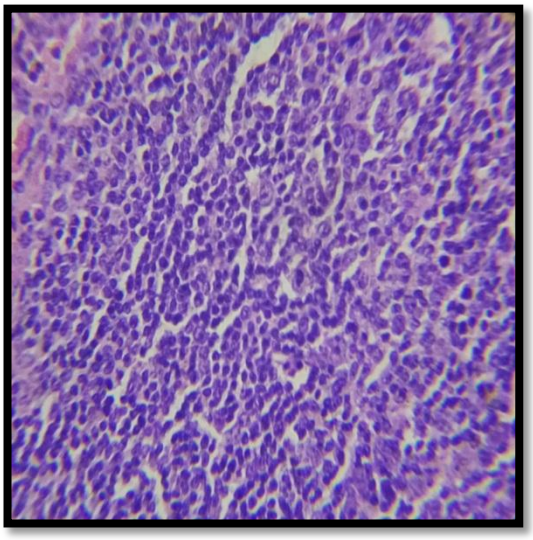


Plate b. Low dose group

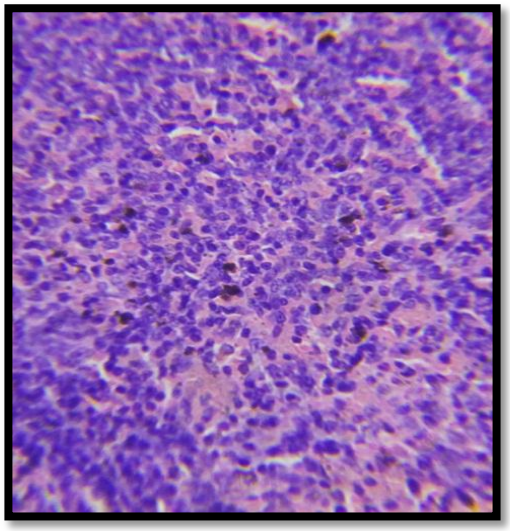


Plate c. Mid dose group

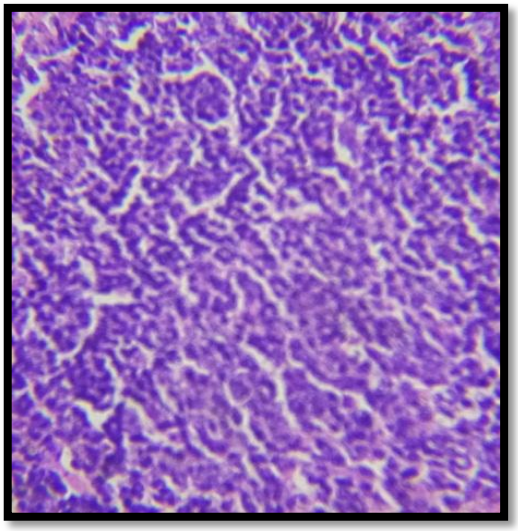


Plate d.High dose group

Plate a

- Appearance of red pulp and marginal sinus are normal. No abnormalities found in lymph nodes

Plate b

- Appearance of marginal sinus was normal
- Lymphoid follicles appears normal. Marginal sinus (MS) of the rat and its sinus lining cells appear normal. Erythropoietic cells (EP) are scattered throughout the red pulp.

Plate c

- Germinal center, Follicle and Central artery appears normal

Plate d

- Mild reduction in cellularity and size of the red pulp

Long term toxicity Study

Histopathology of Kidney

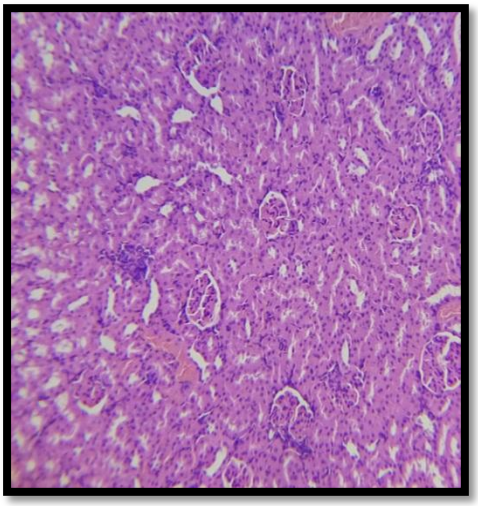


Plate a. Control

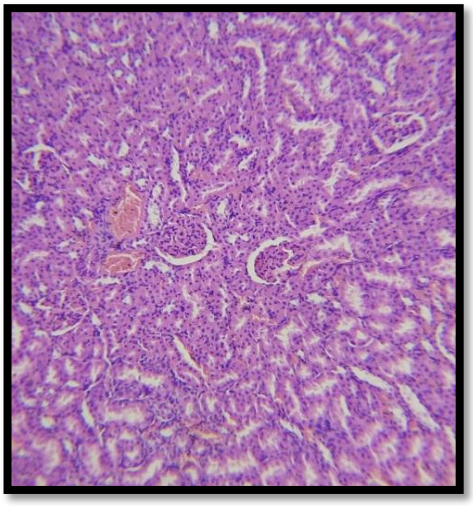


Plate b. Low dose group

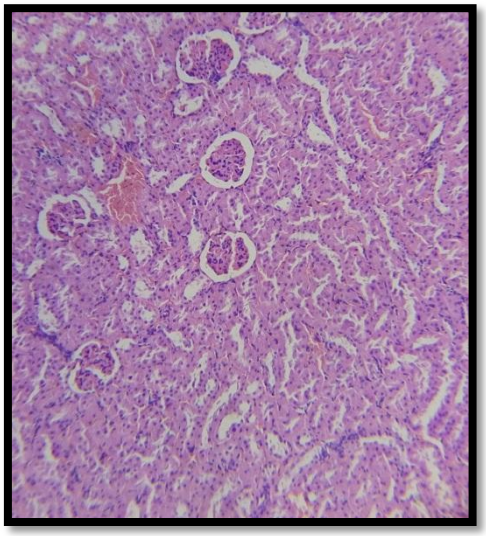


Plate c. Mid dose group

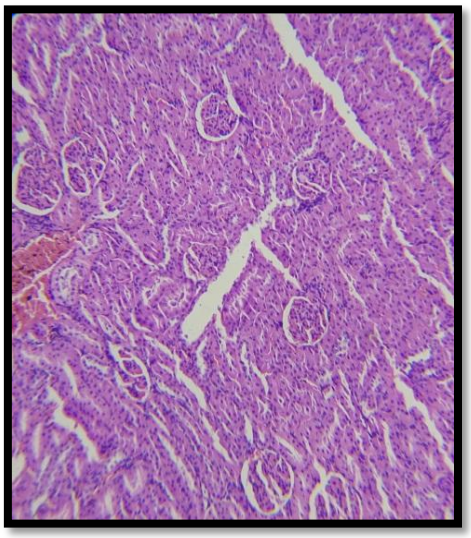


Plate d. High dose group

Plate a

- Glomerulus (G) surrounded by a narrow capsular space and the parietal layer of Bowman's capsule.
- Note the proximal convoluted tubules (P) and the distal convoluted tubules (D)
- Epithelial lining on proximal convoluted tubule appears normal
- Lumen of distal convolutes tubule and collecting duct was normal.

Plate b

- Glomerulus (G) surrounded by a narrow capsular space and the parietal layer of Bowman's capsule.
- Note the proximal convoluted tubules (P) and the distal convoluted tubules (D)
- Epithelial lining on proximal convoluted tubule appears normal

Plate c

- Glomerulus (G) surrounded by a narrow capsular space and the parietal layer of Bowman's capsule.
- Note the proximal convoluted tubules (P) and the distal convoluted tubules (D)
- Epithelial lining on proximal convoluted tubule appears normal

Plate d

- Epithelial lining on proximal convoluted tubule appears normal
- Lumen of distal convolutes tubule and collecting duct was normal.

Long term toxicity Study

Histopathology of Testis

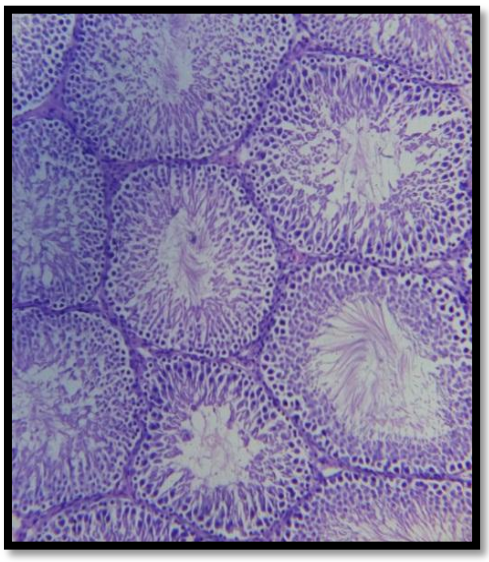


Plate a. Control

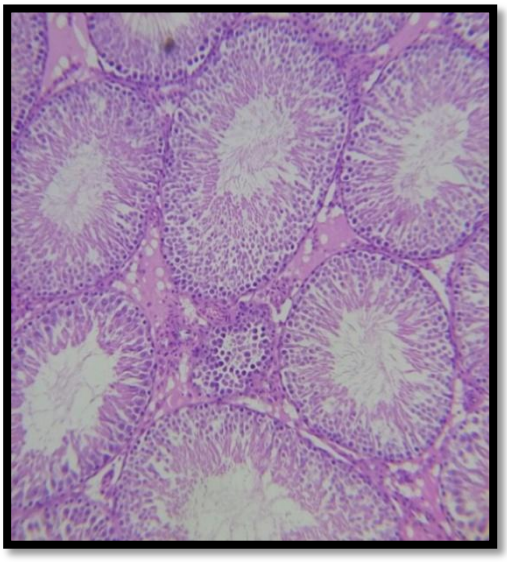


Plate b. Low dose group

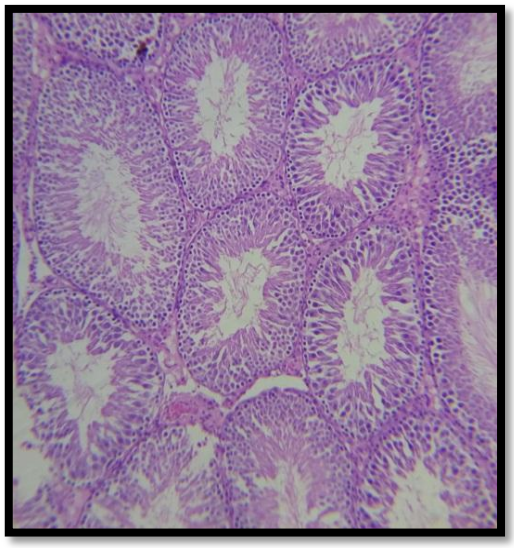


Plate c. Mid dose group

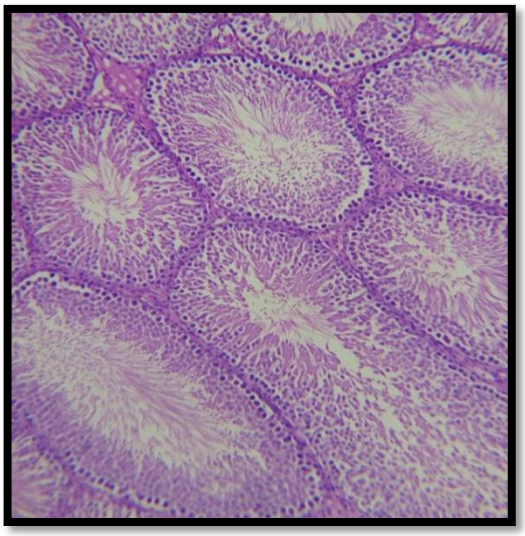


Plate d. High dose group

Plate a

- Presence of mature somatic cells project the perfect histomorphology of testicular cells were observed.
- Primary spermatocytes with large centered nucleus and dense chromatin were observed.

Plate b

- Normal sertoli cell aligned properly on the basement membrane with oval dome shaped nucleus shows the normal morphology of the seminiferous tubule were observed.

Plate c

- Histo cytology of testicular tissue shows well differentiated germ cells with respect of spermatogonia includes spermatid and sperm were observed.

Plate d

- Appearance of leydig cells, interstitial tissue, seminiferous tubule, Sertoli cells and spermatogonia were normal.

Long term toxicity Study

Histopathology of Uterus

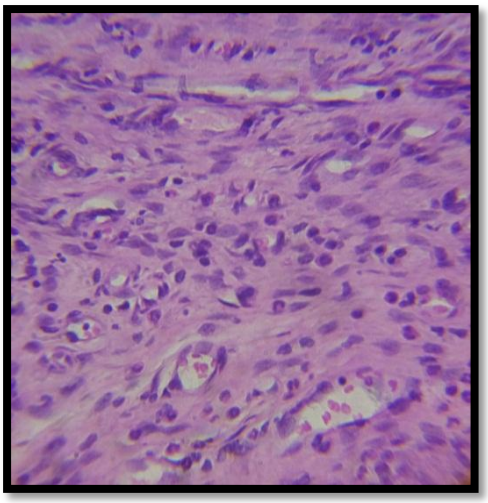


Plate a. Control

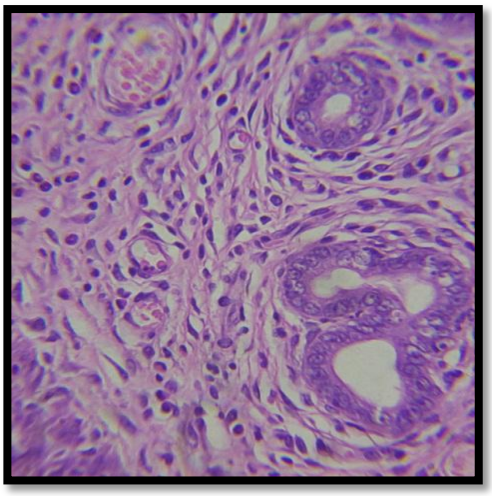


Plate b. Low dose group

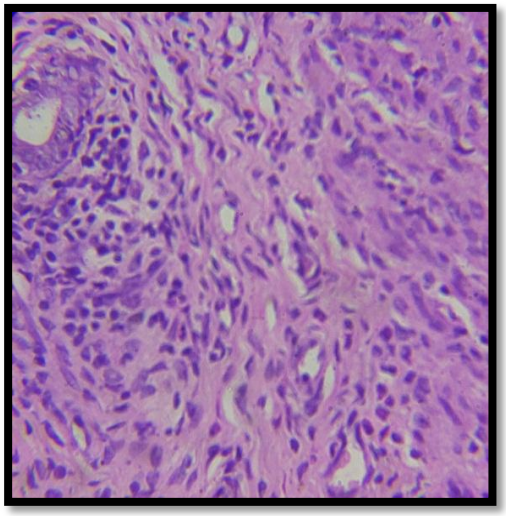


Plate c. Mid dose group

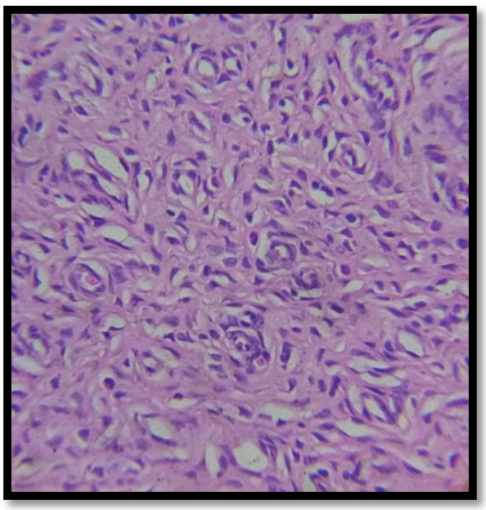


Plate d. High dose group

Plate a

- Appearance of endometrium, myometrium and uterine glands was normal.
- Endometrial gland, epithelium and blood vessels appears normal.

Plate b

- Arrangement of uterine layers such Endometrium and myometrium are normal with no signs of abnormalities.
- Arrangement of stratum basale, functionale and surface epithelium seems normal
- Endometrial gland, epithelium and blood vessels appears normal.

Plate c

- Arrangement of uterine layers such Endometrium and myometrium are normal with no signs of abnormalities.
- Endometrial gland, epithelium and blood vessels appears normal.

Plate d

- Arrangement of uterine layers such Endometrium and myometrium are normal with no signs of abnormalities.
- Arrangement of stratum basale, functionale and surface epithelium seems normal.

Long term toxicity Study

Histopathology of Ovary

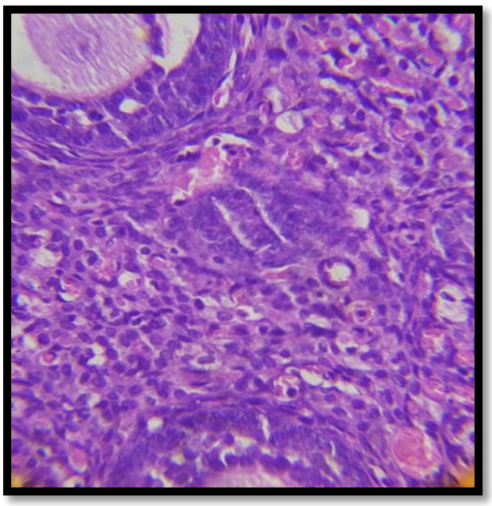


Plate a. Control

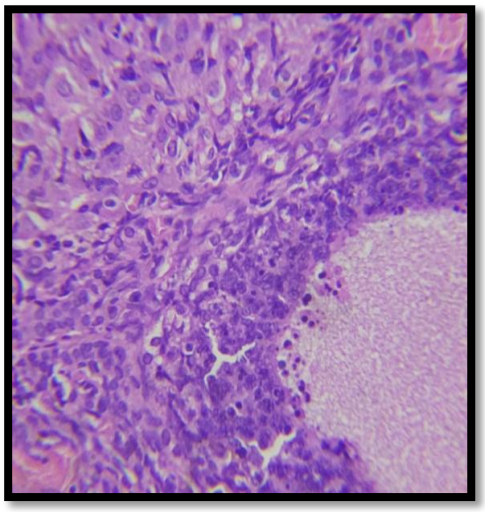


Plate b. Low dose group

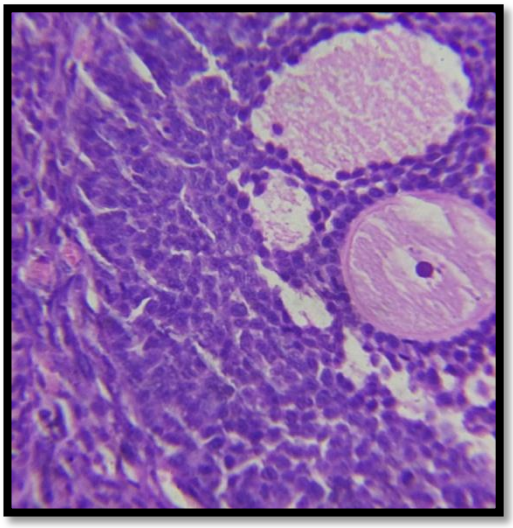


Plate c. Mid dose group

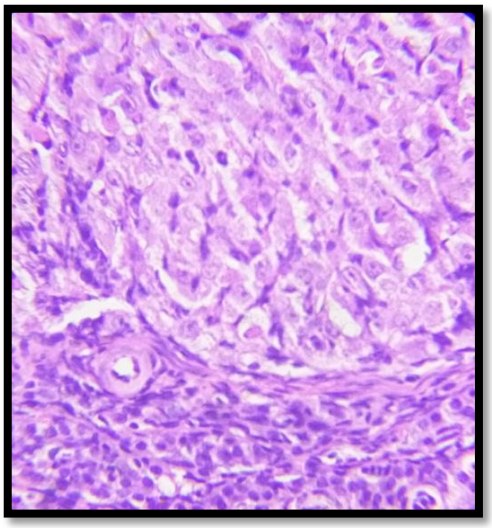


Plate d. High dose group

Plate a

- Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality.

Plate b

- Sequential arrangement of granulosa cells arounds oocyte was normal and regular
- Follicular cells, cytoplasm and nucleus appears normal
- Appearance of antral follicle, primary oocyte and secondary follicles are normal

Plate c

- Histopathological analysis of ovary showing normal corpus luteum (CL) and Primordial follicles with few mature ovarian follicles with no signs of abnormality.

Plate d

- Sequential arrangement of granulosa cells arounds oocyte was normal and regular
- Follicular cells, cytoplasm and nucleus appears normal

Plate e

- Sequential arrangement of granulosa cells arounds oocyte was normal and regular
- Follicular cells, cytoplasm and nucleus appears normal

Long term toxicity Study

Histopathology of Brain

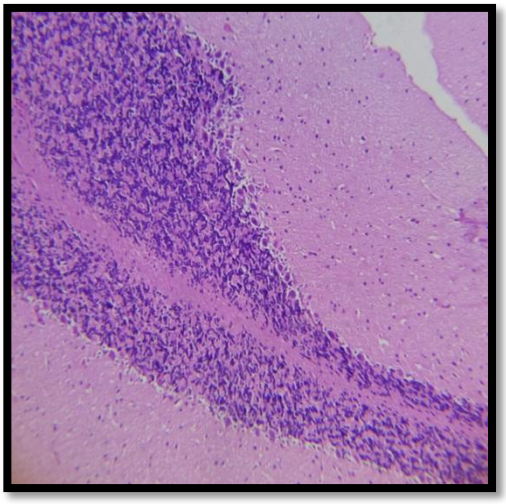


Plate a. Control

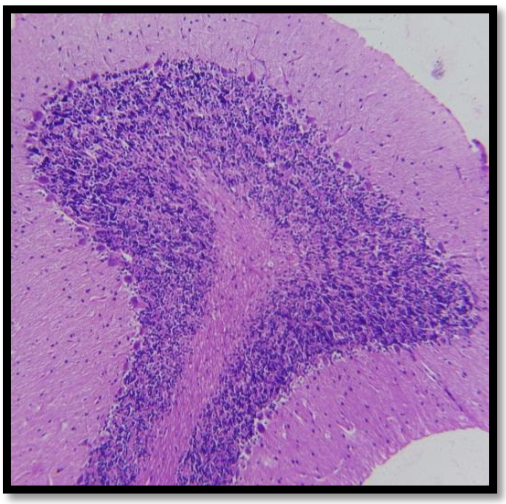


Plate b. High dose

Plate a

- Regular marginal alignment on the neurons with promising histology .Neurons are very intact and there were no signs of oedema or degeneration were observed.
- Section of cerebellum shows distinct molecular and granular layer. Neuronal architecture appears normal with sufficient numbers
- Arrangement of the neurons appears intact with no signs of degeneration or apoptotic changes.

Plate b

- Cortex region showed normal neurons with polygonal to round cell bodies containing dense cytoplasm.
- Normal appearance of cerebral cortex and medulla with intact parenchyma
- Neuronal cellular architecture appears normal with regular inter neuronal space.

CLINICAL STUDY

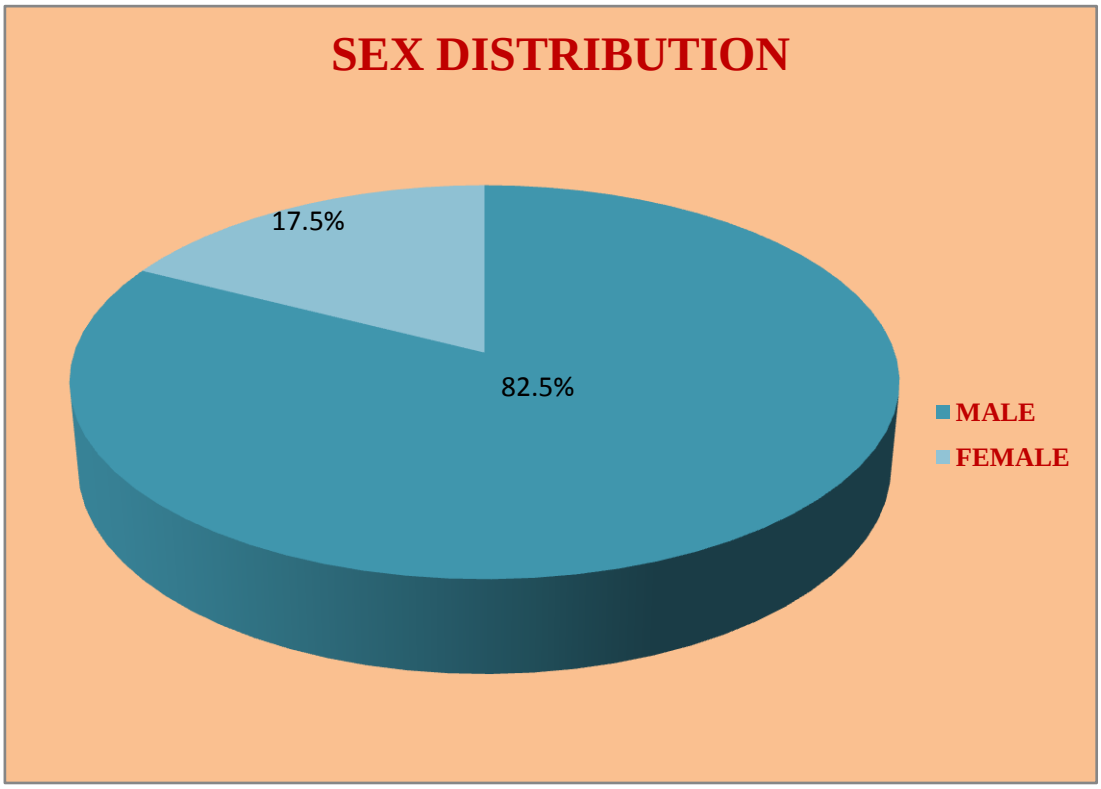
OBSERVATION AND RESULTS

The observation and results were studied and tabulated under the following heading.

1) Sex distribution
2) Age distribution
3) Occupational status
4) Family History
5) Diet habits
6) Thinai reference
7) Kaalam distribution (According to Age)
8) Kaalam distribution
9) Yakkai Ilakkanam (Physical Constitution)
10) Gunam reference
11) Duration of illness
12) Clinical features
13) Distributions of three thodams
14) UdarKattukkal reference
15) En Vagaithervugal
16) Neerkkuri reference
17) Neikkuri reference
18) VCSS Score (Weekly Assesment)
19) Result

1. **Sex distribution:**

S.no	Sex distribution	No of cases	Percentage
1.	Male	33	82.5%
2.	Female	7	17.5%

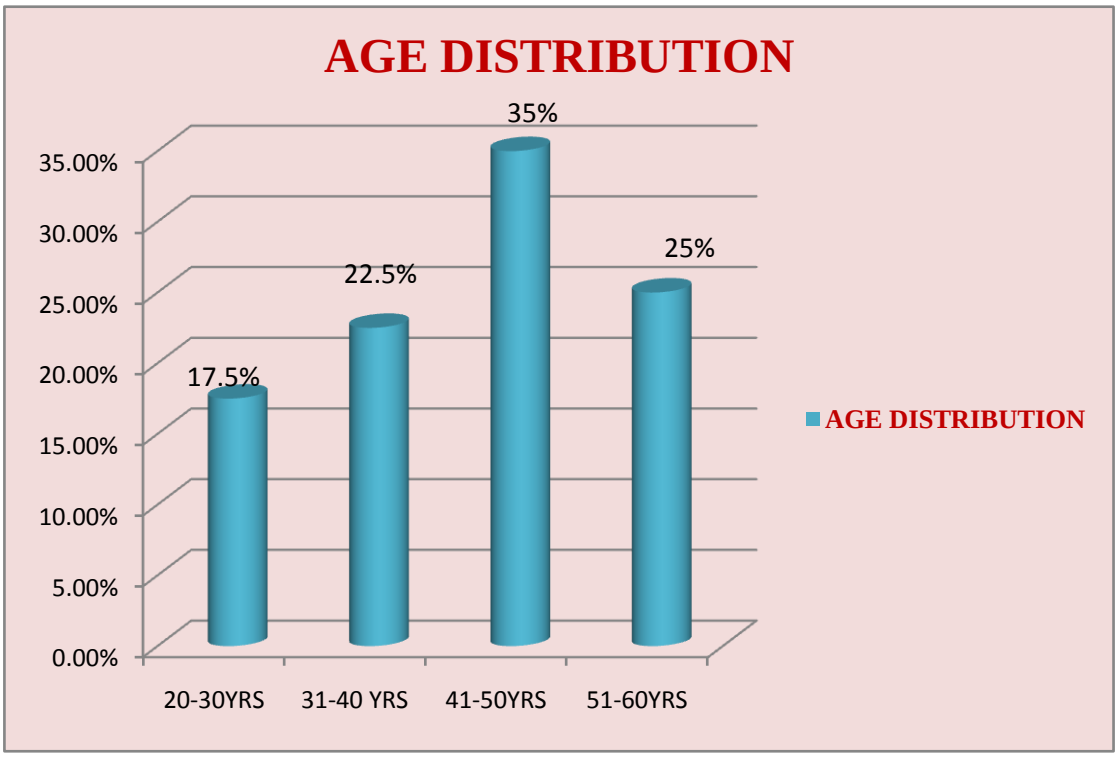


Observation:

Among the 40 patients selected for this study, 82.5% were males and 17.5% females.

2. Age distribution:

S.no	Age	No of cases	Percentage
1.	20–30	7	17.5%
2.	31-40	9	22.5%
3.	41-50	14	35%
4.	51-60	10	25%

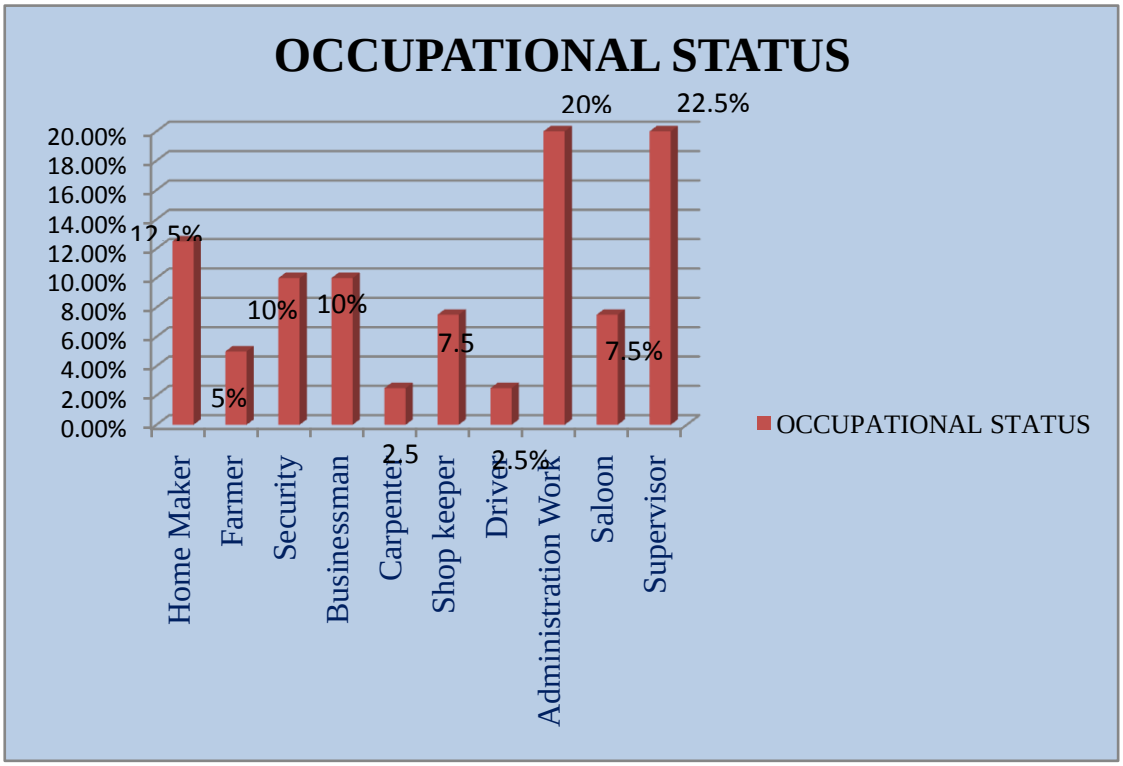


Observation:

The patients were selected from all age groups as given above and the maximum numbers of patients (14) were in the age between 41 and 50yrs.

3. Occupational status:

Sl. No	Nature of Work	No. of Cases	Percentage
1	Home Maker	5	12.5%
2	Farmer	2	5%
3	Security	4	10%
4	Businessman	4	10%
5	Carpenter	1	2.5%
6	Shop keeper	3	7.5%
7	Driver	1	2.5%
8	Administration Work	8	20%
9	Saloon	3	7.5%
10	Supervisor	9	22.5%

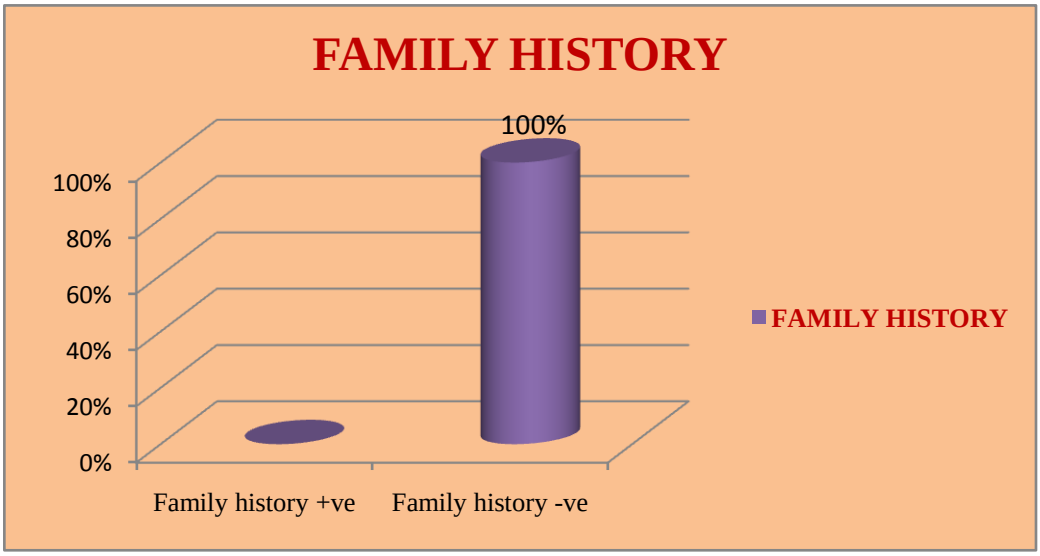


Observation:

The majority of patients in this study were Administration Work & Supervisors.

4. Family history:

S,no	Critaria	No of cases	Percentages
1.	Family history(+ ve)	-	-
2.	Family history(- ve)	40	100%

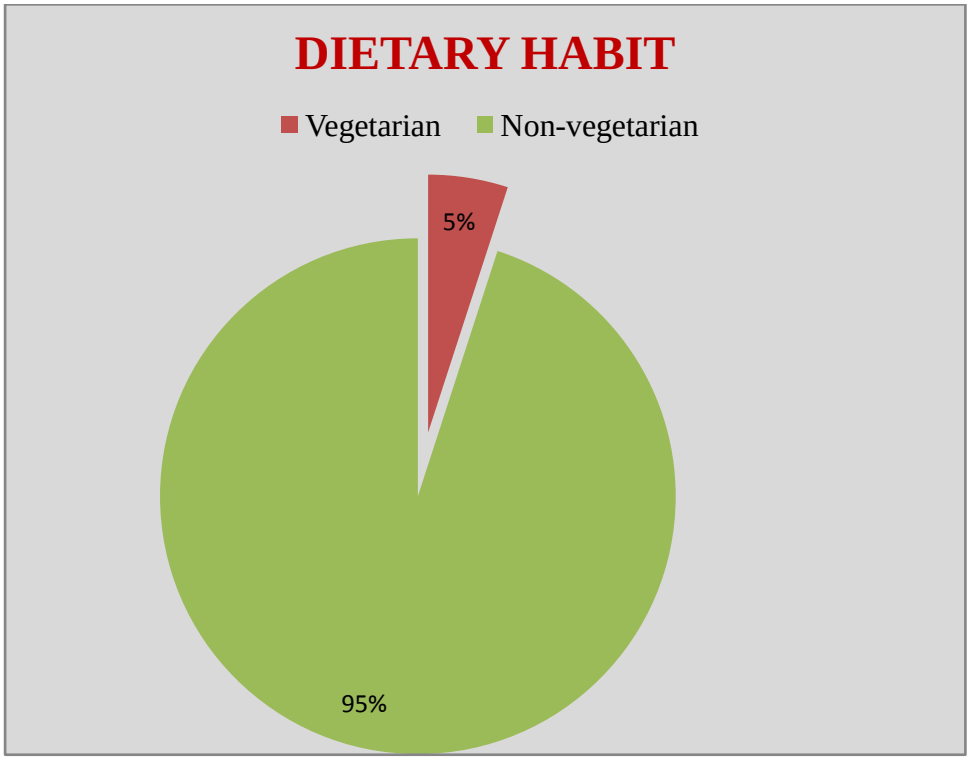


Observation:

100% of the patients showed negative family history.

5. Dietary habits:

S.no	Dietary habits	No of cases	Percentage
1.	Vegetarian	2	5%
2.	Non-vegetarian	38	95%

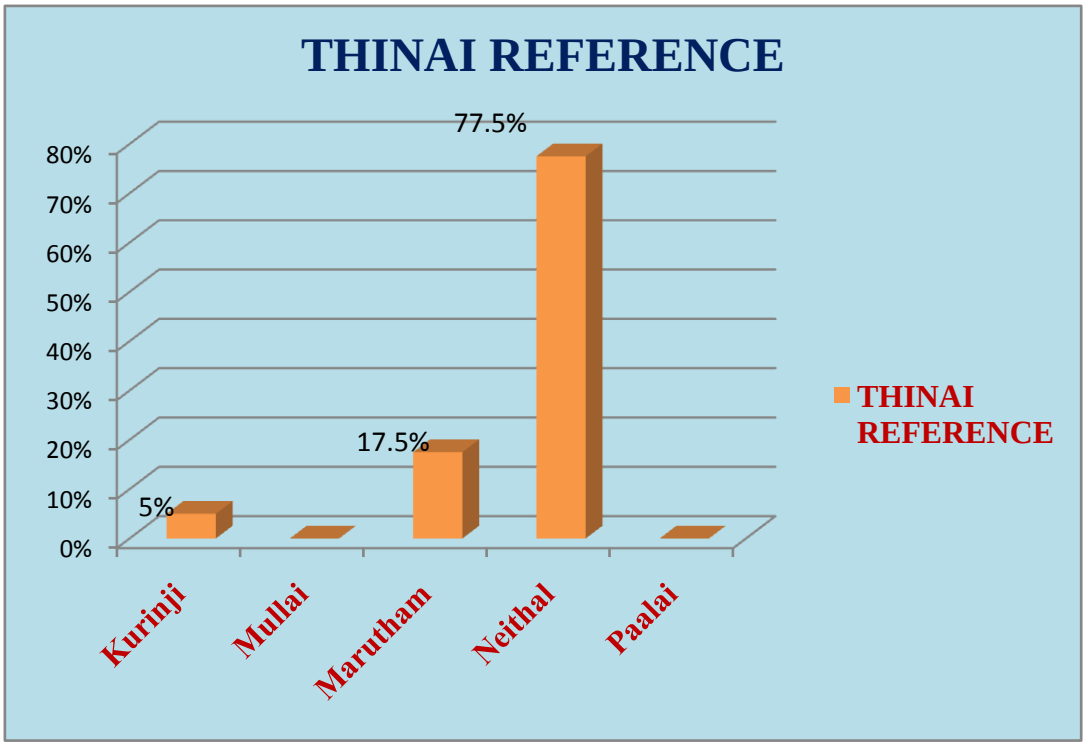


Observation:

95% of the patients were non-vegetarians.

6. Thinai reference:

S.no	Thinai	No of cases	Percentage
1.	Kurinji	2	5%
2.	Mullai	-	-
3.	Marutham	7	17.5%
4.	Neithal	31	77.5%
5.	Paalai	-	-



Observation:

77.5% of the patients were from *Neithal* (Coastal Area) and (17.5%) from *Marutham* (Fertile Land) and the remaining (5%) from kurinji (Hill area)

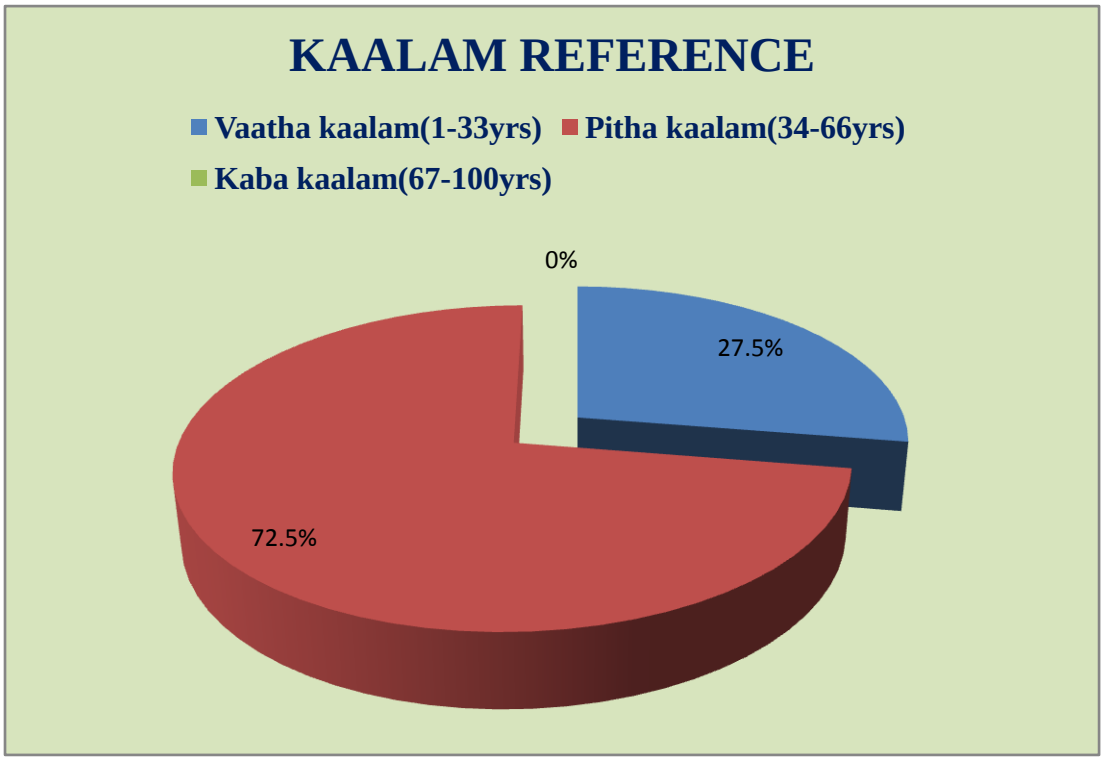
7. Kaalam distribution (According to age)

In Siddha literature human life has been divided into three periods as follows

1) *Vatham*
2) *Piththam*
3) *Kabam*

The duration of each period is said to be 33 years

S.no	Kaalam	No of cases	Percentage
1.	Vaatha kaalam(1-33yrs)	11	27.5%
2.	Pitha kaalam(34-66yrs)	29	72.5%
3.	Kaba kaalam(67-100yrs)	-	-

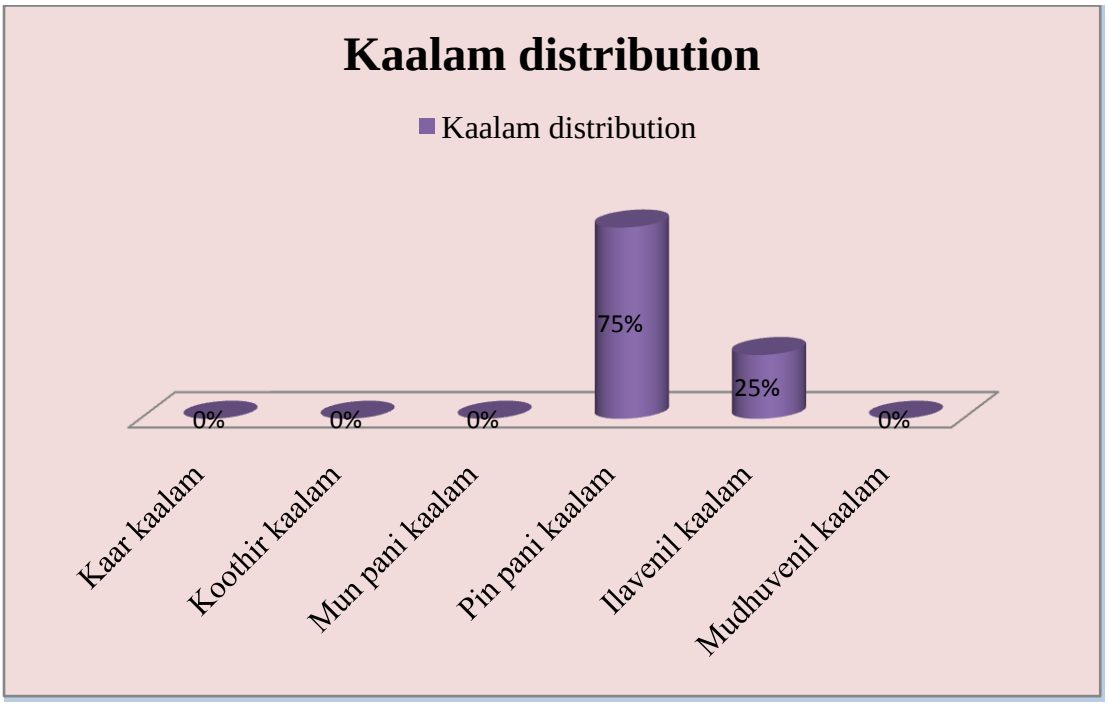


Observation:

72.5% of the patients in *Pithakaalam* and the remaining 27.5% patients reported in *Vathakaalam*.

8. **Kaalam distribution:**

S.no	Kaalam distribution	No of cases	Percentage
1.	Kaar kaalam	-	-
2.	Koothir kaalam	-	-
3.	Mun pani kaalam	-	-
4.	Pin pani kaalam	30	75%
5.	Ilavenil kaalam	10	25%
6.	Mudhuvenil kaalam	-	-

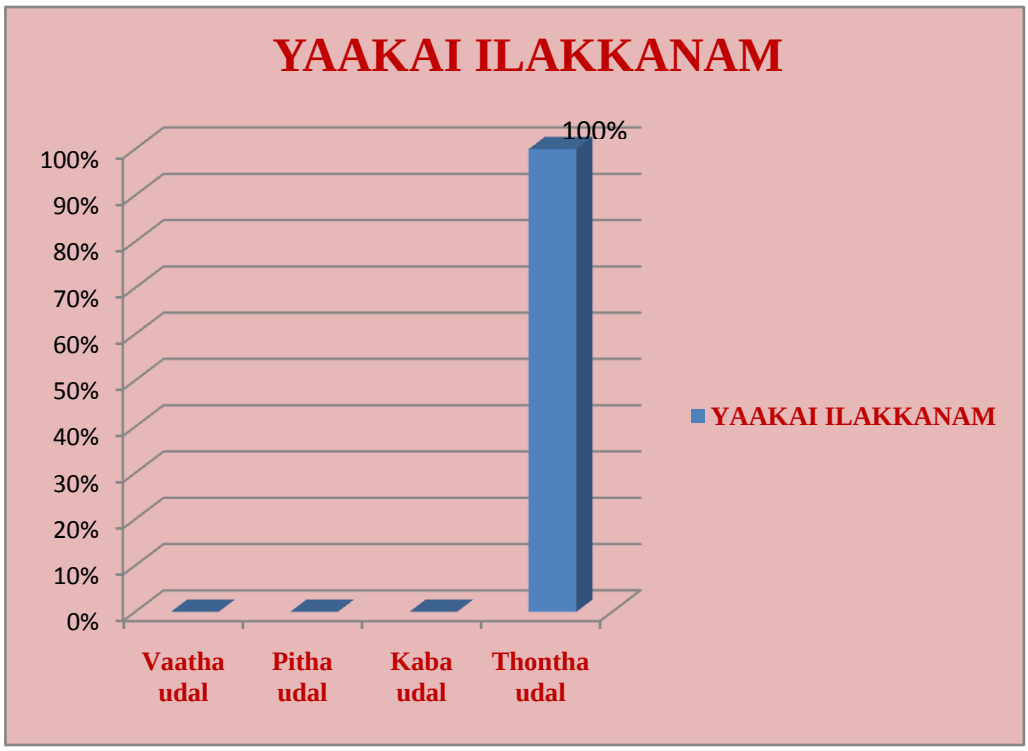


Observation:

75% of the patients admitted in *Pinpanikaalam* and the remaining 25% patients were admitted in *Ilavenilkaalam*.

9. **Yaakai ilakkanam(Physical constituents):**

S.no	Yaakai ilakkanam	No of cases	Percentage
1.	Vaatha udal	-	-
2.	Pitha udal	-	-
3.	Kaba udal	-	-
4.	Thontha udal	40	100%

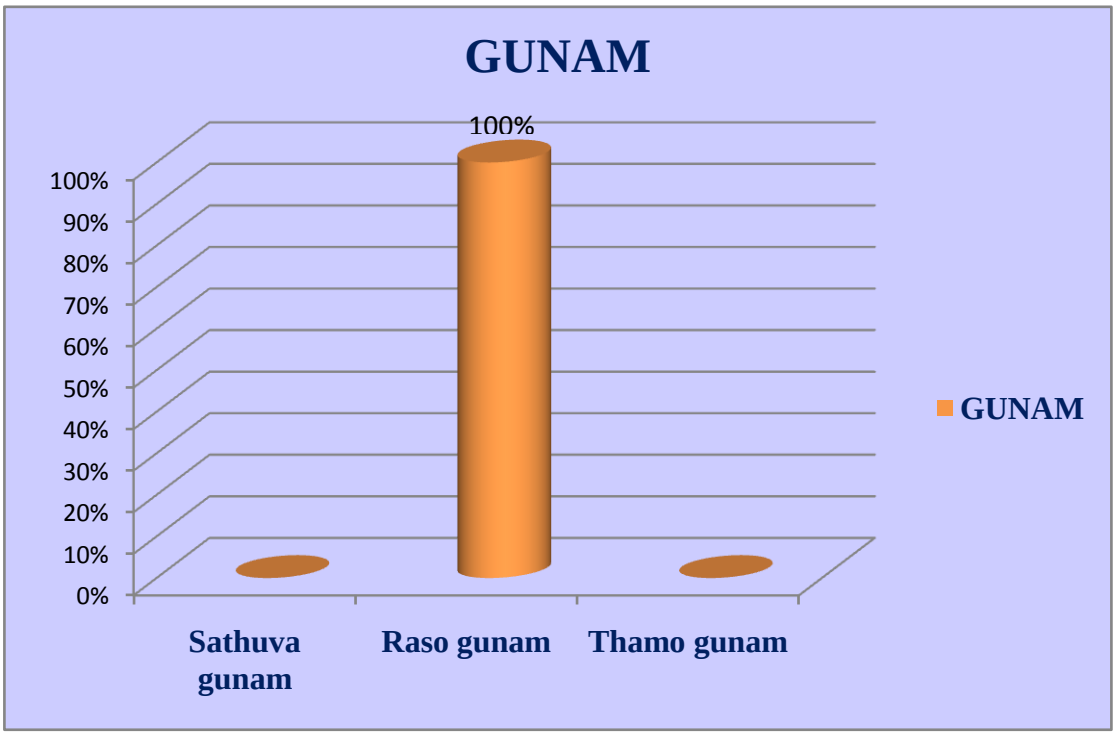


Observation:

All the patients (100%) had *ThonthaUdal*.

10. **Gunam(Quality and Character)**

S.no	Gunam	No of cases	Percentage
1.	Sathuva gunam	-	-
2.	Raso gunam	40	100%
3.	Thamo gunam	-	-

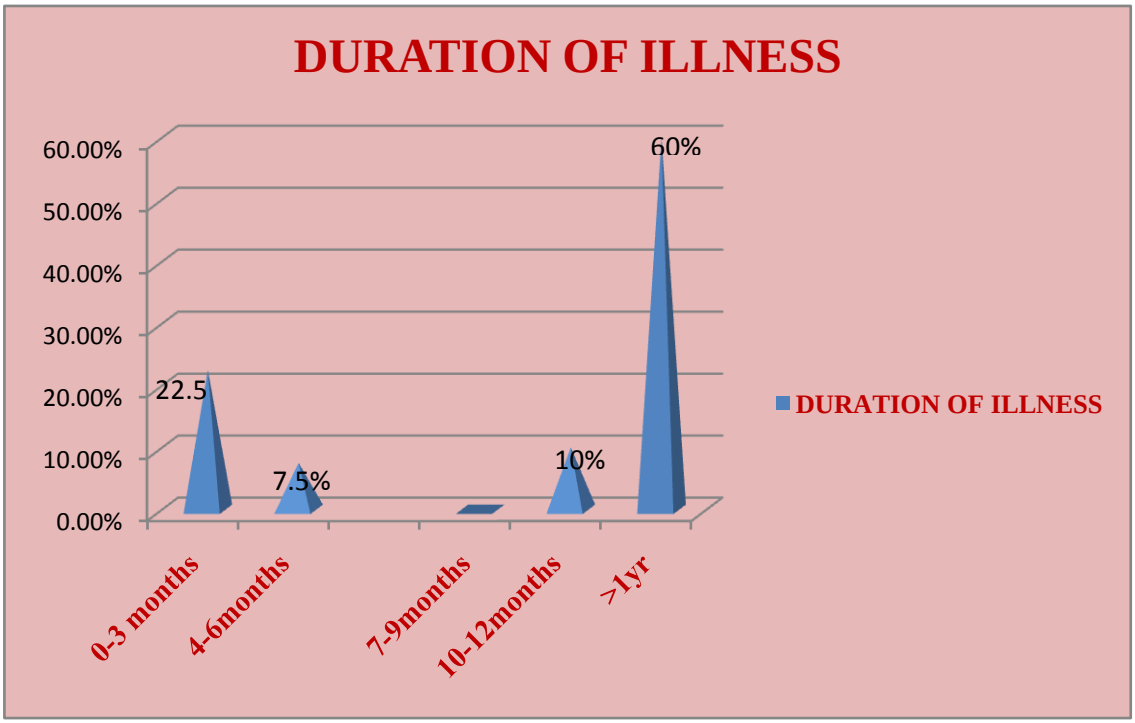


Observation:

All the patients (100%) had "*RasoGunam*".

11. **Duration of illness:**

S.no	Duration of illness	No of cases	Percentage
1.	0-3 months	9	22.5%
2.	4-6months	3	7.5%
3.	7-9months	-	-
4.	10-12months	4	10%
5.	>1yr	24	60%

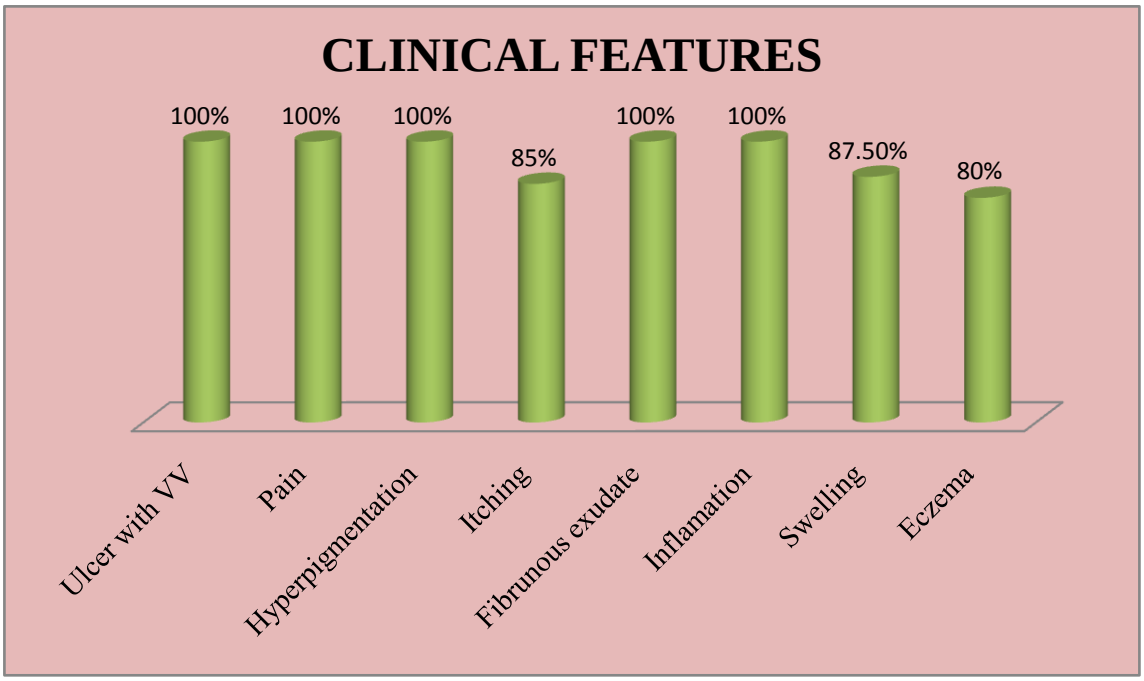


Observation:

60% of the patients were suffering with the illness for more than 1 year.

12. **Clinical features:**

S.no	Clinical features	No of cases	Percentage
1.	Ulcer with varicose vein	40	100%
2.	Pain	40	100%
3.	Hyperpigmentation around the ulcer	40	100%
4.	Itching	34	85%
5.	Fibrunous exudate	40	100%
6.	Inflamation	40	100%
7.	Swelling	35	87.5%
8.	Eczema around the ulcer	32	80%

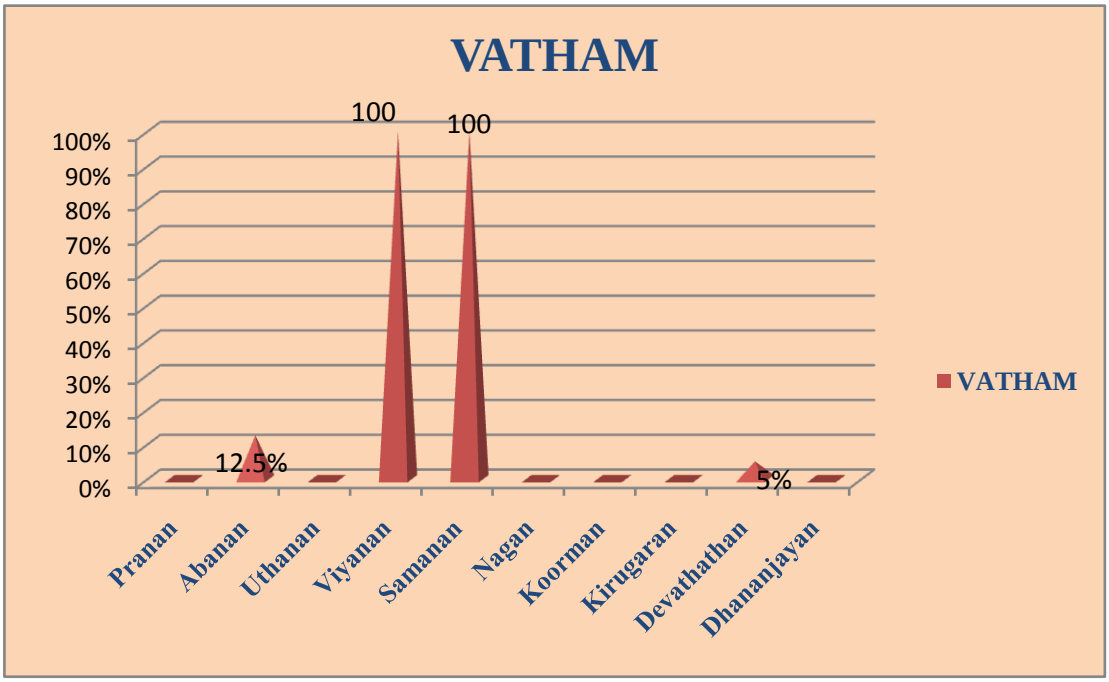


Observation:

All patients in the study had clinical features' of ulcer with varicose vein, oozing, pain, hyperpigmentation, inflammation, 85% with itching, 87.5% with swelling and 80% with eczema around ulcer.

13. **Distribution of Mukkutram:**
Vaatham:

S.no	Vaatham	No of cases	Percentage
1.	Pranan	-	-
2.	Abanan	5	12.5%
3.	Uthanan	-	-
4.	Viyanan	40	100%
5.	Samanan	40	100%
6.	Nagan	-	-
7.	Koorman	-	-
8.	Kirugaran	-	-
9.	Devathathan	2	5%
10.	Dhananjayan	-	-

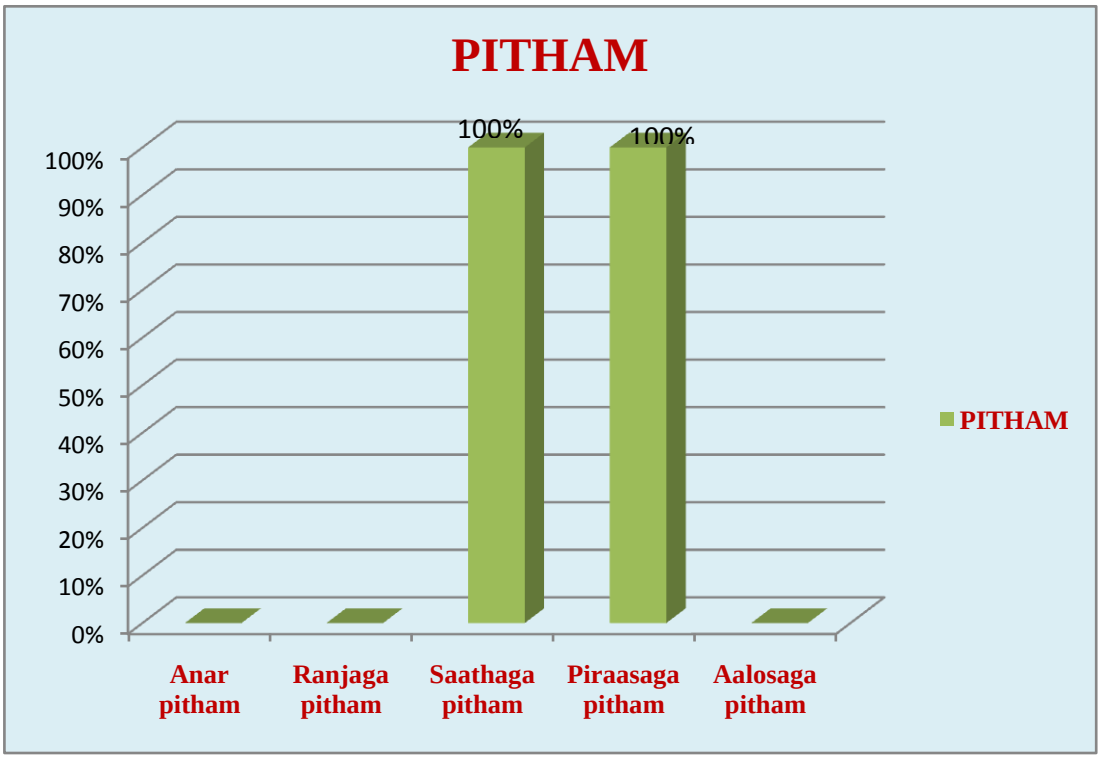


Observation:

Samaanan and *Viyaanan* were affected in all the 40 patients. *Abanan*and *Devathaththan* were affected in 5 and 2 patients respectively

Pitham:

S.no	Pitham	No of cases	Percentage
1.	Anar pitham	-	-
2.	Ranjaga pitham	-	-
3.	Saathaga pitham	40	100%
4.	Piraasaga pitham	40	100%
5.	Aalosaga pitham	-	-

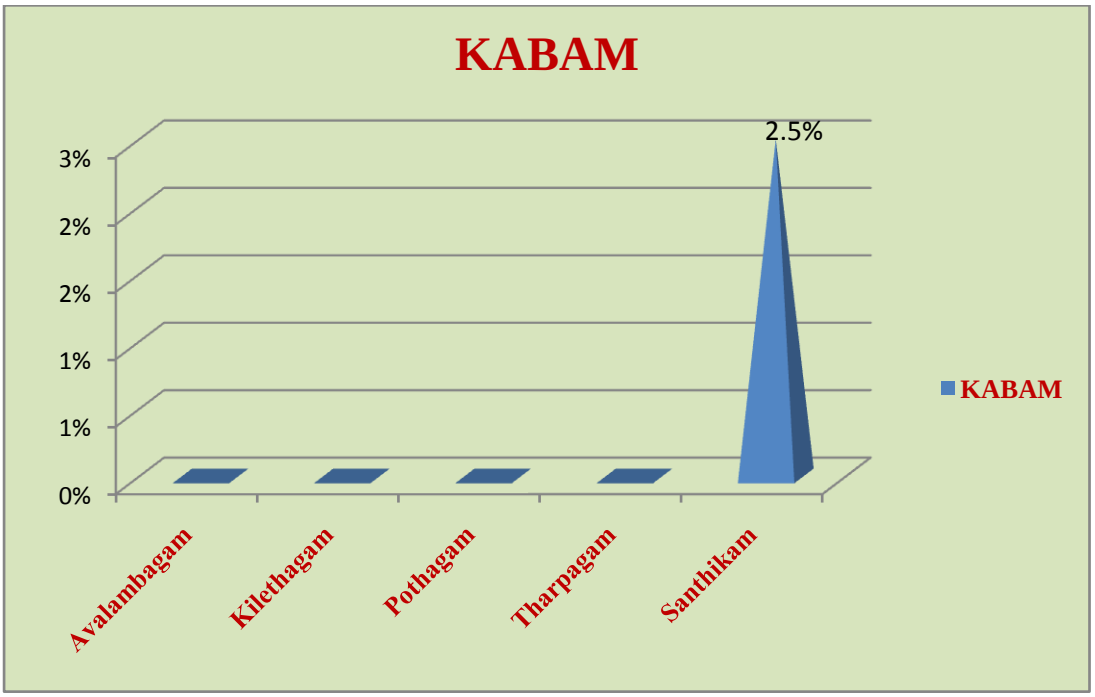


Observation:

Saathaga pitham and *Pirasaga pitham* were affected in all the cases.

Kabam:

S.no	Kabam	No of cases	Percentage
1.	Avalambagam	-	-
2.	Kilethagam	-	-
3.	Pothagam	-	-
4.	Tharpagam	-	-
5.	Santhikam	1	2.5%

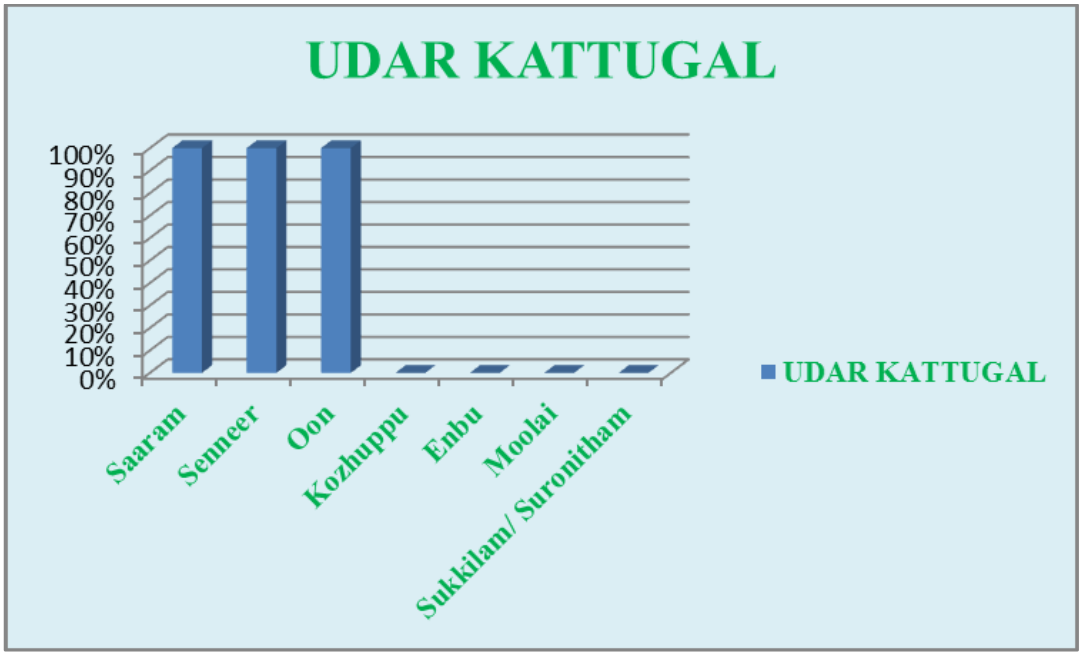


Observation:

In*Kabamsanthikam* was affected in 2.5% cases.

14. **Udar kattugal:**

S.no	Udar kattugal	No of cases	Percentage
1.	Saaram	40	100%
2.	Senneer	40	100%
3.	Oon	40	100%
4.	Kozhuppu	-	-
5.	Enbu	-	-
6.	Moolai	-	-
7.	Sukkilam/ Suronitham	-	-



Observation:

Among 40 patients, *Saaram* and *Seneer* were affected in all the cases.

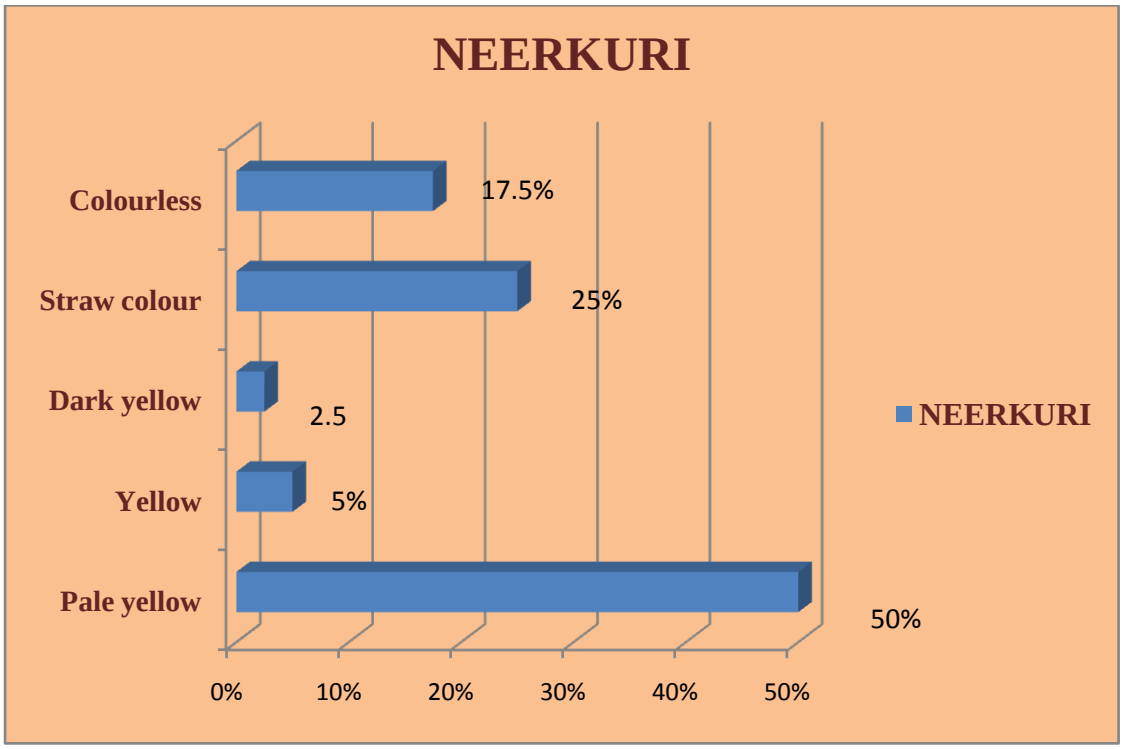
15. **Envagai thervugal:**

Sl. No	Envagai Thervugal	No. of Cases	Percentage
1	Naadi		
	a. Vathapiththam	20	50%
	b. Piththavatham	10	25%
	c. Kaba vatham	4	10%
	d. Kaba piththam	6	15%
2	Sparisam	40	100%
3	Naa	-	-
4	Niram	40	100%
5	Mozhi	-	-
6	Vizhi	-	-
7	Malam	5	12.5%
8	Moothiram	-	-

In *Envagaithervugal*, *Niram* and *Sparisam* were found affected in all the 40 cases. The *Naadinadai* seen in *Naalavibatha pun* patients were *Vathapitham* 50%, *Pithavatham* 25 %, *Kabavatham* 10%, *Kabapitham1*5%.

16. Neerkuri Reference:

S.no	Neerkuri	No of cases	Percentage
1.	Pale yellow	20	50%
2.	Yellow	2	5%
3.	Dark yellow	1	2.5%
4.	Straw colour	10	25%
5.	Colourless	7	17.5%

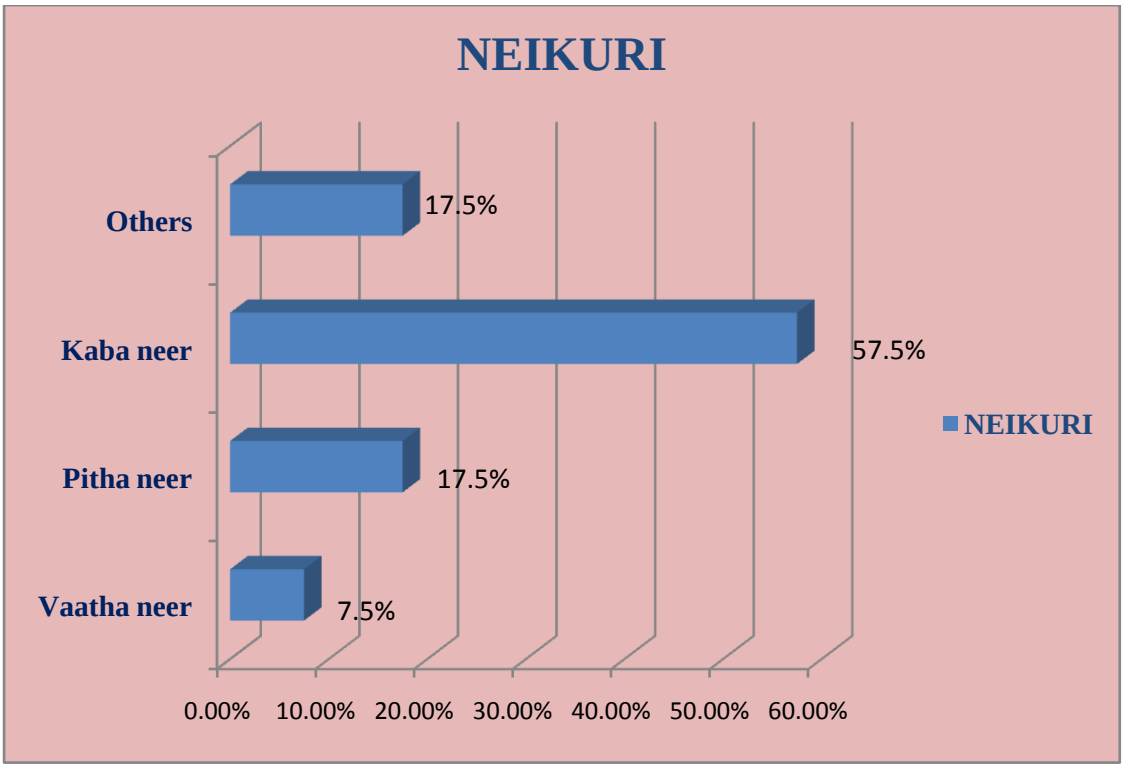


Observation:

In this study 50% of the patients had *Neerkkuri* with pale yellow, 5% with yellow, 2.5% with colourless,25% with dark yellow and 17.5% with straw colour.

17. **Neikuri Reference:**

S.no	Neikuri	No of cases	Percentage
1.	Vaatham(Aravena neendathu)	3	7.5%
2.	Pitham(Aazhi pol paraviyathu	7	17.5%
3.	Kabam(Muthothu ninrathu)	23	57.5%
	Others	7	17.5%



Observation:

In this study 7.5% of the patients had *Neikuri* with *Vatham (Aravana Neendal),*17.5% with *Piththam(Azhipol Paraviyathu),* 57.5% with *Kabam(Muthothu ninrathu)* and 17.5% with other pattern.

18. VCSS SCORE (Weekly assessment)

OP/IP no	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day
I 66207	16	13	10	9	7	6	5
I 60252	23	21	19	18	15	10	5
H 68569	18	18	17	16	14	13	12
H 13974	19	17	16	16	15	15	13
I 67217	13	12	10	9	7	2	1
IP-9448	17	16	13	10	8	6	2
I 40853	16	14	12	10	8	6	2
H 83931	16	15	13	11	8	7	2
IP-9469	20	18	15	14	12	9	4
H 61480	20	20	18	17	14	11	5
F 009361	18	16	16	13	10	6	2
I 74686	18	16	15	13	11	9	4
I 69996	12	11	10	10	9	5	2
IP-8817	21	21	18	17	15	14	9
IP-9502	23	20	17	15	13	9	5
I 25352	17	15	12	10	8	4	4
IP-9507	18	17	15	12	10	7	5
IP-8824	23	21	19	18	18	17	16
I8356	18	17	16	14	13	11	11
I 21367	17	17	16	14	13	12	10

VCSS SCORE (Weekly assessment)

OP/IP no	1st day	8th day	15th day	22nd day	29th day	36th day	43rd day
H 5501	21	21	18	15	15	14	14
I 77918	19	17	16	14	12	10	6
I 78657	18	16	14	12	10	7	2
G28368	13	13	11	9	7	5	2
I 33083	20	20	16	15	13	12	11
I 41069	22	21	18	16	14	12	9
IP-9540	16	15	14	11	9	6	2
G 42979	18	17	15	13	10	8	5
I 78214	14	13	11	9	8	7	3
IP-8910	18	17	13	11	10	8	4
I 82898	14	13	13	11	10	5	3
I 78956	20	18	17	15	13	11	7
I 88996	18	18	17	15	14	10	7
IP-9580	20	18	15	11	10	8	4
I 90263	14	13	13	12	10	8	5
IP- 9588	19	16	13	10	7	5	2
I 81527	21	19	17	17	14	11	5
I 92135	22	20	18	17	16	14	9
I 16273	17	15	14	13	11	9	4
I 89809	20	18	17	15	15	9	7

OUT COME

S. No.	OP/IP NO.	NAME	AGE / SEX	BT	AT	VCSS	RESULT
1	I 66207	D.SENTHIL	32/M	16	5	75%	Good
2	I 60252	K.A.SIVAGURU	53/M	23	5	79%	Good
3	H 68569	N.MUNUSAMY	50/M	18	12	39%	Mild
4	H 13974	B.CHENGAMMAL	48/F	19	12	37%	Mild
5	I 67217	C.K.UMESH	36/M	13	1	93.3%	Good
6	IP-9448	P.SEKAR	42/M	17	2	88.3%	Good
7	I 40853	G.SHANTHI	38/F	16	2	87.5%	Good
8	H 83931	M.KANNAN	46/M	16	2	87.5%	Good
9	IP-9469	N.PARANTHAMAN	53/M	20	4	80%	Good
10	H 61480	T.KAMALAKANNAN	50/M	20	5	75%	Good
11	F 009361	N.VINCENT	46/M	18	2	89%	Good
12	I 74686	T.S.MAGESH	39/M	18	4	78%	Good
13	I 69996	P.KAVIMANI	28/M	12	2	84%	Good
14	IP-8817	V.NIRMALA	45/F	21	9	58%	Moderate
15	IP-9502	A.K.PERUMAL	47/M	23	5	79%	Good
16	I 25352	K.THANGARAJ	52/M	17	4	76.5%	Good
17	IP-9507	B.VIJAYAKUMAR	59/M	18	3	83.4%	Good
18	IP-8824	M.BHAVANI	20/F	23	16	30.5%	Mild
19	I8356	S.KRISHNAMOORTHY	21/M	18	11	38.9%	Mild
20	I 21367	P.SURESH	51/M	17	10	42%	Mild

OUT COME

S. No.	OP NO.	NAME	AGE / SEX	BT	AT	VCSS	RESULT
21	H 5501	K.CHOKKUSAMY	54/M	21	14	34%	Mild
22	I 77918	C.KAILASH	29/M	19	6	68.5%	Moderate
23	I 78657	N.DURAI RAJ	43/M	18	2	88.9%	Good
24	G28368	N.PALANI	44/M	13	2	85%	Good
25	I 33083	S.JAYAKUMAR	56/M	20	11	45%	Mild
26	I 41069	P.RATHAKRISHNAN	52/M	22	9	59%	Moderate
27	IP-9540	S.SUBASH	44/M	16	2	87.5%	Good
28	G 42979	M.SAKTHIVEL	42/M	18	5	72.5%	Moderate
29	I 78214	K.NARESHKUMAR	32/M	14	3	78.6%	Good
30	IP-8910	R.CHELLAMMAL	56/F	18	4	77.8%	Good
31	I 82898	N.MURALIDHARAN	27/M	14	3	79%	Good
32	I 78956	A.M.GOPI	33/M	20	7	65%	Moderate
33	I 88996	J.PARTHIBAN	26/M	18	7	62%	Moderate
34	IP-9580	K.MURUGESAN	47/M	20	4	80%	Good
35	I 90263	D.GOPALAKRISHNAN	28/M	14	5	64%	Moderate
36	IP- 9588	E.PRAVEEN	33/M	19	2	89.5%	Good
37	I 81527	A.SUDHAKAR	40/M	21	5	76%	Good
38	I 92135	V.NITHYA	40/F	22	9	59%	Good
39	I 16273	A.KUMAR	41/M	17	4	76.5%	Good
40	I 89809	D.DEVI	56/F	20	7	65%	Moderate

NOTE:-

BT : Before Treatment; **AT :** After Treatment;

VCSS SCORE: -

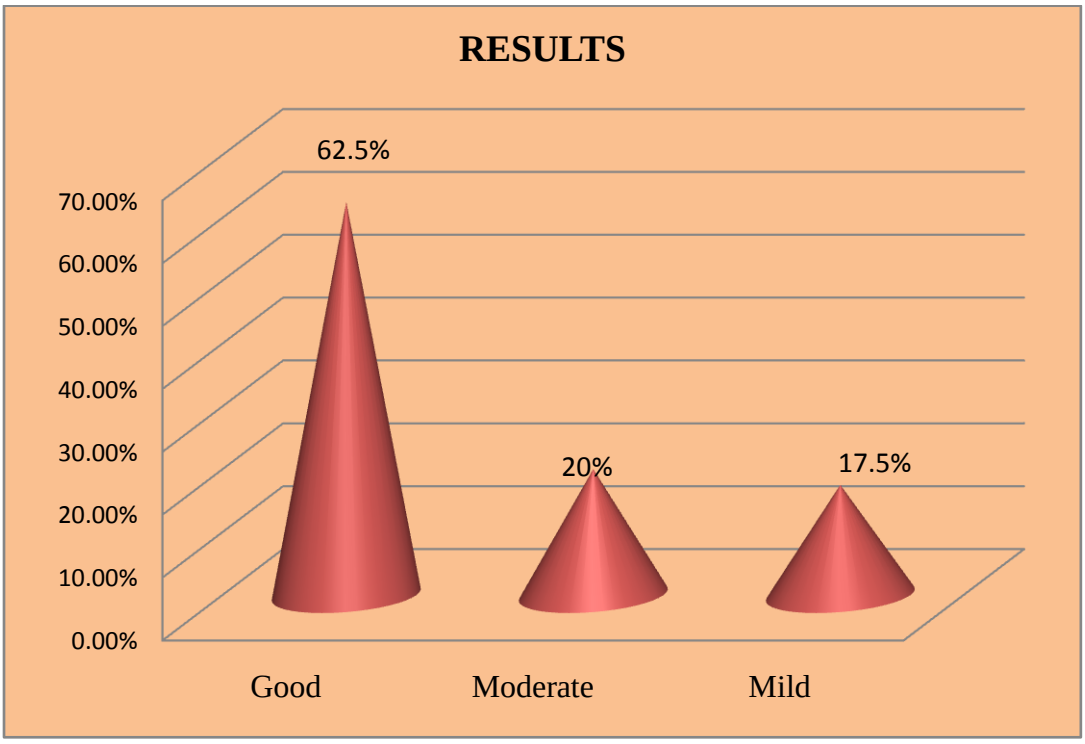
*** VCSS0-25** = 0-25% **(Poor)** reduction in the VCSS Score in before and after treatment.

*** VCSS25-50 =**25-50% **(Mild)** reduction in the VCSS Score in before and after treatment.
*** VCSS50-75 =**50-75% **(Moderate)** reduction in the VCSS Score in before and after treatment.
*** VCSS 75-100 =** 75-100% **(Good)** reduction in the VCSS Score in before and after treatment.

19. RESULTS:

The trial drug *Kukkil chooranam*(Internal) and *Thuvara ennai* (External) were given to 40 patients for 48 days.

Sl. No	Results	No of Cases	Percentage
1	Good	25	62.5%
2	Moderate	8	20%
3	Mild	7	17.5%



Observation:

The trial drug *Kukkil chooranam*(Internal) and *Thuvara ennai* (External) were given to 40 patients for 48 days.Good improvement was observed in 25 patients (62.5%), moderate improvement in 8 patients (20%), and mild improvement in 7 (17.5%) cases

Mr.S.Subash, 44/M. VCSS SCORE

Before treatment - 16

After treatment - 2

Result- 87.5% improved – Good

Mr.B.Vijayakumar, 59/M.

Before treatment – 18 (VCSS SCORE)

After treatment – 3 (VCSS SCORE)

Result – 83.4% improved – Good

Mr.K.Nareshkumar, 32/M.

Before treatment – 14 (VCSS SCORE)

After treatment -3(VCSS SCORE)

Result -78.6 % improved-- Good

LABORATORY INVESTIGATIONS

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	IP / OP NO.	NAME	AGE / SEX	Hb (gm/dl)		TOTAL RBC COUNT (mill/cu.mm)		ESR (mm/hour)		TOTAL WBC (cells/cu.mm)	
				BT	AT	BT	AT	BT	AT	BT	AT
1	I 66207	D.SENTHIL	32/ M	13.9	12	5	4.9	8	8	7900	7800
2	I 60252	K.A.SIVAGURU	53/ M	14.9	14	5.5	5.2	12	18	9400	7600
3	H 68569	N.MUNUSAMY	50/ M	11.3	10.8	4.2	3.9	32	70	6100	6100
4	H 13974	B.CHENGAMMAL	48/ F	9	8.8	3.7	3.5	132	112	7900	7300
5	I 67217	C.K.UMESH	36/ M	16	14.9	5.4	5	12	10	5800	6400
6	IP-9448	P.SEKAR	42/ M	14.3	13.4	5.1	4.6	40	52	8100	8800
7	I 40853	G.SHANTHI	38/ F	12	11.2	5.2	4.7	20	20	8400	7000
8	H 83931	M.KANNAN	46/ M	12.9	13.2	4	3.9	40	30	6400	8300
9	IP-9469	N.PARANTHAMAN	53/ M	11.9	12.2	4.4	4.4	60	90	7800	5000
10	H 61480	T.KAMALAKANNAN	50/ M	13.1	12.5	5.2	4.9	44	80	9700	12500
11	F 009361	N.VINCENT	46/ M	14.5	14	4.7	4.5	12	12	6600	7000
	I 74686	T.S.MAGESH	39/ M	15.1	15	5	4.9	4	4	6400	6400
13	I 69996	P.KAVIMANI	28/ M	18.4	18	5.5	5.6	8	6	13000	10700
14	IP-8817	V.NIRMALA	45/ F	12.5	12.1	4.5	4.6	12	40	4800	6500
15	IP-9502	A.K.PERUMAL	47/ M	12.9	13.4	4.5	4.6	86	52	8700	8800
16	I 25352	K.THANGARAJ	52/ M	14	14	4.8	4.5	12	12	8000	7900
17	IP-9507	B.VIJAYAKUMAR	59/ M	12	11.9	4.1	4.1	20	42	9300	8800
18	IP-8824	M.BHAVANI	20/ F	8.9	8.9	3.7	4	Too high	60	7700	7600
19	I8356	S.KRISHNAMOORTHY	21/ M	14.8	14.6	4.9	4.7	12	22	7300	6700
20	I 21367	P.SURESH	51/ M	14.4	14	4.6	4.6	12	14	6300	6300

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	IP / OP No.	NAME	AGE / SEX	SGOT (IU/L)		SGPT (IU/L)		Alkaline phosphatase	
				BT	AT	BT	BT	BT	AT
1	I 66207	D.SENTHIL	32/M	22	20	18	18	65	70
2	I 60252	K.A.SIVAGURU	53/M	19	19	19	14	73	68
3	H 68569	N.MUNUSAMY	50/M	14	14	17	15	65	74
4	H 13974	B.CHENGAMMAL	48/F	11	11	17	31	48	46
5	I 67217	C.K.UMESH	36/M	18	18	28	23	87	77
6	IP-9448	P.SEKAR	42/M	11	18.6	20	21.8	70	78
7	I 40853	G.SHANTHI	38/F	15	17	4	11	78	66
8	H 83931	M.KANNAN	46/M	10	17	12	18	58	60
9	IP-9469	N.PARANTHAMAN	53/M	20	18	13	13	69	65
10	H 61480	T.KAMALAKANNAN	50/M	12	15	14	16	200	152
11	F 009361	N.VINCENT	46/M	21	30	24	28	50	66
12	I 74686	T.S.MAGESH	39/M	18	20	29	28	66	70
13	I 69996	P.KAVIMANI	28/M	29	15	20	13	78	101
14	IP-8817	V.NIRMALA	45/F	25	13	19	17	63	73
15	IP-9502	A.K.PERUMAL	47/M	17	16.6	11	11.5	72	71
16	I 25352	K.THANGARAJ	52/M	13	14	12	13	104	101
17	IP-9507	B.VIJAYAKUMAR	59/M	13.6	14	18.4	15	59	66
18	IP-8824	M.BHAVANI	20/F	13.6	20	10	10	79	78
19	I8356	S.KRISHNAMOORTHY	21/M	22	19	28	24	72	75
20	I 21367	P.SURESH	51/M	18	20	19	22	67	69

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S.No.	OP No.	NAME	AGE / SEX	SGOT (IU/L)		SGPT (IU/L)		Alkaline phosphatase	
				BT	AT	BT	AT	BT	AT
21	H 5501	K.CHOKKUSAMY	54/M	19	18	14	25	125	143
22	I 77918	C.KAILASH	29/M	24	20	30	28	60	66
23	I 78657	N.DURAI RAJ	43/M	15	19	18	21	70	73
24	G28368	N.PALANI	44/F	14	20	13	12	71	80
25	I 33083	S.JAYAKUMAR	56/M	18	21	13	15	104	103
26	I 41069	P.RATHAKRISHNAN	52/M	11	14	16	21	82	82
27	IP-9540	S.SUBASH	44/M	10	9	18	13	72	65
28	G 42979	M.SAKTHIVEL	42/M	44	48	60	50	90	96
29	I 78214	K.NARESHKUMAR	32/M	52	18	6	16	105	101
30	IP-8910	R.CHELLAMMAL	56/F	14	16	12	20	69	70
31	I 82898	N.MURALIDHARAN	27/M	18	20	13	25	63	70
32	I 78956	A.M.GOPI	33/M	40	25	32	37	89	86
33	I 88996	J.PARTHIBAN	26/M	28	20	61	23	116	98
34	IP-9580	K.MURUGESAN	47/M	22	17	25	11	70	66
35	I 90263	D.GOPALAKRISHNAN	28/M	30	28	30	29	60	65
36	IP- 9588	E.PRAVEEN	33/M	23	9.7	27.6	8.2	89	83
37	I 81527	A.SUDHAKAR	40/M	13.9	14	11.7	20	81	82
38	I 92135	V.NITHYA	40/F	18	20	20	25	102	110
39	I 16273	A.KUMAR	41/M	23	14	29	15	111	85
40	I 89809	D.DEVI	56/F	20	25	15	20	68	70

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	IP / OP NO.	NAME	AGE / SEX	TOTAL BILIRUBIN		DIRECT BILIRUBIN		INDIRECT BILIRUBIN	
				BT	AT	BT	AT	BT	AT
1	I 66207	D.SENTHIL	32/M	0.7	0.8	0.3	0.4	0.4	0.4
2	I 60252	K.A.SIVAGURU	53/M	0.6	0.4	0.2	0.2	0.4	0.2
3	H 68569	N.MUNUSAMY	50/M	0.8	0.4	0.4	0.2	0.5	0.2
4	H 13974	B.CHENGAMMAL	48/F	0.5	0.3	0.2	0.1	0.3	0.2
5	I 67217	C.K.UMESH	36/M	1	0.8	0.3	0.3	0.7	0.5
6	IP-9448	P.SEKAR	42/M	0.8	0.5	0.3	0.215	0.5	0.3
7	I 40853	G.SHANTHI	38/F	0.7	0.6	0.3	0.3	0.4	0.3
8	H 83931	M.KANNAN	46/M	0.5	0.6	0.3	0.2	0.2	0.4
9	IP-9469	N.PARANTHAMAN	53/M	0.6	0.5	0.2	0.2	0.4	0.3
10	H 61480	T.KAMALAKANNAN	50/M	0.2	0.2	0.1	0.1	0.1	0.1
11	F 009361	N.VINCENT	46/M	2.2	1.8	0.8	0.9	1.4	0.9
12	I 74686	T.S.MAGESH	39/M	0.7	0.8	0.3	0.4	0.4	0.4
13	I 69996	P.KAVIMANI	28/M	0.4	0.3	0.2	0.2	0.2	0.1
14	IP-8817	V.NIRMALA	45/F	0.8	0.7	0.3	0.3	0.5	0.4
15	IP-9502	A.K.PERUMAL	47/M	0.4	0.44	0.2	0.29	0.2	0.2
16	I 25352	K.THANGARAJ	52/M	0.4	0.6	0.2	0.3	0.2	0.3
17	IP-9507	B.VIJAYAKUMAR	59/M	0.29	0.4	0.141	0.3	0.1	0.1
18	IP-8824	M.BHAVANI	20/F	0.35	0.4	0.179	0.2	0.2	0.2
19	I8356	S.KRISHNAMOORTHY	21/M	0.5	0.5	0.2	0.3	0.3	0.2
20	I 21367	P.SURESH	51/M	0.6	0.8	0.3	0.4	0.3	0.4

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S.NO.	OPNO.	NAME	AGE / SEX	TOTAL BILIRUBIN		DIRECT BILIRUBIN		INDIRECT BILIRUBIN	
				BT	AT	BT	AT	BT	AT
21	H 5501	K.CHOKKUSAMY	54/M	0.6	0.5	0.2	0.3	0.4	0.2
22	I 77918	C.KAILASH	29/M	0.7	0.7	0.3	0.3	0.4	0.4
23	I 78657	N.DURAI RAJ	43/M	0.6	0.5	0.2	0.2	0.4	0.3
24	G28368	N.PALANI	44/F	1.2	0.8	0.5	0.4	0.7	0.4
25	I 33083	S.JAYAKUMAR	56/M	0.4	0.5	0.2	0.2	0.2	0.3
26	I 41069	P.RATHAKRISHNAN	52/M	0.7	0.5	0.3	0.2	0.4	0.3
27	IP-9540	S.SUBASH	44/M	0.5	0.4	0.2	0.2	0.3	0.2
28	G 42979	M.SAKTHIVEL	42/M	1.6	0.8	0.5	0.4	1.1	0.4
29	I 78214	K.NARESHKUMAR	32/M	1.6	1.7	0.6	0.7	1	1
30	IP-8910	R.CHELLAMMAL	56/F	0.4	0.6	0.2	0.3	0.2	0.3
31	I 82898	N.MURALIDHARAN	27/M	3	1.8	0.6	0.8	2.4	1
32	I 78956	A.M.GOPI	33/M	1.2	0.9	0.4	0.4	0.8	0.5
33	I 88996	J.PARTHIBAN	26/M	0.7	0.7	0.3	0.3	0.4	0.4
34	IP-9580	K.MURUGESAN	47/M	0.7	0.6	0.2	0.3	0.4	0.3
35	I 90263	D.GOPALAKRISHNAN	28/M	0.9	0.9	0.3	0.4	0.6	0.5
36	IP- 9588	E.PRAVEEN	33/M	1.56	0.62	0.67	0.31	0.83	0.3
37	I 81527	A.SUDHAKAR	40/M	0.59	0.6	0.25	0.3	0.3	0.3
38	I 92135	V.NITHYA	40/F	0.5	0.7	0.2	0.3	0.3	0.4
39	I 16273	A.KUMAR	41/M	1.4	1.5	0.5	0.6	0.9	0.9
40	I 89809	D.DEVI	56/F	0.6	0.8	0.3	0.5	0.3	0.3

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	IP / OP No.	NAME	AGE / SEX	BLOOD (mg/dl)				UREA		CREATININE (mg/dl)	
				FASTING (mg/dl)		POST PRANDIAL (mg/dl)					
				BT	AT	BT	AT	BT	AT	BT	AT
1	I 66207	D.SENTHIL	32/M	100	105	124	120	19	18	1	1
2	I 60252	K.A.SIVAGURU	53/M	94	97	128	96	23	27	1.1	1.2
3	H 68569	N.MUNUSAMY	50/M	100	96	116	116	24	28	1.1	1
4	H 13974	B.CHENGAMMAL	48/F	102	108	120	110	26	35.9	0.9	1.2
5	I 67217	C.K.UMESH	36/M	106	100	93	76	26	21	1.3	1.2
6	IP-9448	P.SEKAR	42/M	99	93	126	129	12	20.6	0.9	1.8
7	I 40853	G.SHANTHI	38/F	100	85	118	112	11	17	0.9	0.8
8	H 83931	M.KANNAN	46/M	103	93	115	109	13	16	1	1.1
9	IP-9469	N.PARANTHAMAN	53/M	93	89	115	102	18	18	1	1.1
10	H 61480	T.KAMALAKANNAN	50/M	115	113	116	158	15	14	1	1
11	F 009361	N.VINCENT	46/M	102	102	92	112	15	15	1	1.1
12	I 74686	T.S.MAGESH	39/M	113	110	105	120	19	20	1	1
13	I 69996	P.KAVIMANI	28/M	100	88	82	90	17	14	1.1	1
14	IP-8817	V.NIRMALA	45/F	92	110	109	118	17	22	0.7	0.9
15	IP-9502	A.K.PERUMAL	47/M	111	85.3	117	116	29	37.8	1	0.96
16	I 25352	K.THANGARAJ	52/M	103	110	114	120	37	35	1.7	1.1
17	IP-9507	B.VIJAYAKUMAR	59/M	97	107	119	123	17.9	14	0.88	0.9
18	IP-8824	M.BHAVANI	20/F	98	99	109	111	14.4	20	0.94	1
19	I8356	S.KRISHNAMOORTHY	21/M	102	94	119	98	24	11	1	1.1
20	I 21367	P.SURESH	51/M	111	110	114	112	19	20	1	1

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	OPNo.	NAME	AGE / SEX	BLOOD (mg/dl)				UREA		CREATININE (mg/dl)	
				FASTING (mg/dl)		POST PRANDIAL (mg/dl)					
				BT	AT	BT	AT	BT	AT	BT	AT
21	H 5501	K.CHOKKUSAMY	54/ M	114	123	126	126	18	21	1	1
22	I 77918	C.KAILASH	29/ M	97	90	122	130	15	14	0.9	1
23	I 78657	N.DURAI RAJ	43/ M	106	92	112	110	26	20	1.1	1
24	G28368	N.PALANI	44/ F	98	100	126	117	13	12	1.1	1
25	I 33083	S.JAYAKUMAR	56/ M	88	98	113	110	21	23	1.2	1.2
26	I 41069	P.RATHAKRISHNAN	52/ M	107	115	134	117	13	16	1	0.9
27	IP-9540	S.SUBASH	44/ M	108	107	119	108	19	14	1	1
28	G 42979	M.SAKTHIVEL	42/ M	82	91	103	110	17	13	0.9	0.9
29	I 78214	K.NARESHKUMAR	32/ M	100	107	116	116	13	13	1	1
30	IP-8910	R.CHELLAMMAL	56/ F	104	105	138	112	22	40	1.1	1
31	I 82898	N.MURALIDHARAN	27/ M	83	90	72	100	16	20	1.3	1.2
32	I 78956	A.M.GOPI	33/ M	108	107	120	112	30	17	1	0.9
33	I 88996	J.PARTHIBAN	26/ M	92	91	113	116	39	26	1	0.9
34	IP-9580	K.MURUGESAN	47/ M	94	82	144	112	18	17	1.3	0.8
35	I 90263	D.GOPALAKRISHNAN	28/ M	99	100	130	121	22	22	1.3	1.2
36	IP- 9588	E.PRAVEEN	33/ M	113.5	110	133	113.3	19.8	24.3	1.26	0.99
37	I 81527	A.SUDHAKAR	40/ M	110	108	147	120	39.4	40	1.01	1
38	I 92135	V.NITHYA	40/ F	98	90	110	110	23	20	4.5	5.2
39	I 16273	A.KUMAR	41/ M	108	105	121	120	28	21	1	0.8
40	I 89809	D.DEVI	56/ F	108	107	115	120	25	26	1.1	1

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	IP / OP No.	NAME	AGE / SEX	URINE SUGAR (F)		URINE SUGAR (PP)		ALBUMIN		DEPOSITS			
										Epithelial cells		Pus cells	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
1	I 66207	D.SENTHIL	32/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2
2	I 60252	K.A.SIVAGURU	53/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	2-4
3	H 68569	N.MUNUSAMY	50/ M	NIL	NIL	NIL	NIL	NIL	NIL	2-3	1-2	2-3	2-4
4	H 13974	B.CHENGAMMAL	48/ F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-4	1-2
5	I 67217	C.K.UMESH	36/ M	NIL	NIL	NIL	NIL	NIL	NIL	2-3	1-2	6-7	1-2
6	IP-9448	P.SEKAR	42/ M	NIL	NIL	NIL	NIL	NIL	NIL	2-3	2-4	6-7	2-4
7	I 40853	G.SHANTHI	38/ F	NIL	NIL	NIL	NIL	NIL	NIL	2-4	1-2	2-4	1-2
8	H 83931	M.KANNAN	46/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	2-3
9	IP-9469	N.PARANTHAMAN	53/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-4	2-3
10	H 61480	T.KAMALAKANNAN	50/ M	NIL	NIL	NIL	NIL	NIL	NIL	4-5	1-2	1-2	2-3
11	F 009361	N.VINCENT	46/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-4	1-2	1-2
12	I 74686	T.S.MAGESH	39/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-4	3-5	3-5
13	I 69996	P.KAVIMANI	28/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	3-5	1-2	1-2
14	IP-8817	V.NIRMALA	45/ F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-4	3-5	2-4
15	IP-9502	A.K.PERUMAL	47/ M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	2-4	2-4
16	I 25352	K.THANGARAJ	52/ M	NIL	NIL	NIL	NIL	NIL	NIL	2-3	2-4	2-3	2-4
17	IP-9507	B.VIJAYAKUMAR	59/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-3	1-2	1-2
18	IP-8824	M.BHAVANI	20/ F	NIL	NIL	NIL	NIL	NIL	NIL	6-8	6-8	8-10	8-10
19	I8356	S.KRISHNAMOORTHY	21/ M	NIL	NIL	NIL	NIL	NIL	NIL	2-3	1-2	2-3	1-2
20	I 21367	P.SURESH	51/ M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-4	1-2

INVESTIGATIONS BEFORE AND AFTER TREATMENT

S. No.	IP / OP No.	NAME	AGE / SEX	URINE SUGAR (F)		URINE SUGAR (PP)		ALBUMIN		DEPOSITS			
										Epithelial cells		Pus cells	
				BT	AT	BT	AT	BT	AT	BT	AT	BT	AT
21	H 5501	K.CHOKKUSAMY	54 /M	NIL	NIL	NIL	NIL	NIL	NIL	3-5	1-2	2-4	2-4
22	I 77918	C.KAILASH	29 /M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	2-4	2-4
23	I 78657	N.DURAI RAJ	43 /M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	1-3	4-5	2-4
24	G28368	N.PALANI	44 /F	NIL	NIL	NIL	NIL	NIL	NIL	2-4	1-2	2-4	1-2
25	I 33083	S.JAYAKUMAR	56 /M	NIL	NIL	NIL	NIL	NIL	NIL	4-5	1-2	1-2	1-2
26	I 41069	P.RATHAKRISHNAN	52 /M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-4	1-2	2-4
27	IP-9540	S.SUBASH	44 /M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-4	1-2	4-6
28	G 42979	M.SAKTHIVEL	42 /M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-4	3-5
29	I 78214	K.NARESHKUMAR	32 /M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	2-4	1-2	2-4
30	IP-8910	R.CHELLAMMAL	56 /F	NIL	NIL	NIL	NIL	NIL	NIL	3-5	3-5	3-5	2-4
31	I 82898	N.MURALIDHARAN	27 /M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	4-5	2-4
32	I 78956	A.M.GOPI	33 /M	NIL	NIL	NIL	NIL	NIL	NIL	4-5	2-4	1-2	2-4
33	I 88996	J.PARTHIBAN	26 /M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	6-7	6-7	Loaded
34	IP-9580	K.MURUGESAN	47 /M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-3	1-2
35	I 90263	D.GOPALAKRISHNAN	28 /M	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	2-4	2-4
36	IP- 9588	E.PRAVEEN	33 /M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	2-4	2-4
37	I 81527	A.SUDHAKAR	40 /M	NIL	NIL	NIL	NIL	NIL	NIL	2-4	2-4	2-4	1-2
38	I 92135	V.NITHYA	40 /F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	1-2	1-2
39	I 16273	A.KUMAR	41 /M	NIL	NIL	NIL	NIL	NIL	NIL	6-8	1-2	plenty	8-10
40	I 89809	D.DEVI	56 /F	NIL	NIL	NIL	NIL	NIL	NIL	1-2	1-2	3-5	2-4

STATISTICAL ANALYSIS

STATISTICAL ANALYSIS

All collected data were entered into MS Excel software using different columns as variables and rows as patients. SPSS software was used to perform statistical analysis. Basic descriptive statistics include frequency distributions and cross-tabulations were performed. The quantity variables were expressed as Mean ± Standard Deviation and qualitative data as percentage. A probability value of <0.05 was considered to indicate as statistical significance. Paired't' test was performed for determining the significance between before and after treatment.

Paired Sample Statistics (VCSS Score Before Treatment and After Treatment)

Variable	Obs	Mean±SD	t Value	p Value
Before treatment	40	18.17±2.8	t=24.38	p <0.0001)
After treatment	40	5.67±3.77		

The mean± standard deviation of VCSS score at before and after treatment were 18.17±2.8 and 5.67±3.77 respectively which is statistically extremely significant (t=24.38, p=0.0001).

Reduction of VCSS Score before and after treatment

VCSS score	No of patients Before treatment	After treatment
<10	0	33
10-15	6	7
16-20	26	0
21-25	8	0

DISCUSSION

DISCUSSION

The varicose ulcer (VU) is one of the most severe manifestations of chronic venous insufficiency (CVI) of the lower limbs, a disease of great importance to public health due to its high incidence and prevalence and because of the high socioeconomic impact that it brings, since it is difficult to treat and requires prolonged work absenteeism.

The trial drugs were prepared in Gunapadam lab of National Institute of Siddha after the authentication of the raw drugs by Assistant professor of medicinal botany NIS and CCRS Arumbakkam, Chennai.The trail drug was prepared by standard operating procedure as mentioned in the Protocol.

The Bio chemical analysis was done at the biochemistry lab of NIS and the results were documented. The Bio-chemical analysis of *Kukkil chooranam* had shown the presence of **Chloride, Phosphate, Carbonate, Calcium, Potassium, Nitrite, Iron, Tannic acid, starch and Alkaloids**.

In **Short term** carried out as per WHO guideline, there was no treatment-related death or signs of toxicity developed in albino rats at dosage levels of 2000mg/kg body weight through out the study period. Further, no gross pathological changes have been seen in the internal organs of both control and treated groups. Thus, the LD_{50} value was found to be greater than 2000mg/kg body weight, and this provides direct relevance for protecting human and animal health.

To ensure the safety of Kukkil Chooranam, **Long term Toxicity Study** was also carried out as per WHO guideline. Except for hyperactivity at the time of drug administration, no other signs of toxicity were noted. After blood collection, all the animals were euthanized for gross pathological examinations of all major internal organs. The blood samples were sent to a lab for hematological and biochemical analysis. The organs were weighed and preserved in 10% buffered formalin solution before sending for histopathological study. All there ports were statistically analyzed.

Kukkil Chooranam no Significant in Food intake the test group animals were observed when compared with control group during the study period(Table7,8,&Figure2,3) The hemopoietic system serves as an important target for toxic chemicals and is a sensitive index for pathological conditions both in humans

and animals.In Haematological parameters, it had been observed normal in high dose level (Table11&Figure 6, 7, 8, 9, 10, 11). Transaminases (SGOT and SGPT) are good indicators of liver function and biomarkers to predict the possible toxicity of drugs. Any elevation pertaining to these enzymes indicate their out flow into the blood stream due to damage in liver parenchymal cells, there was normal limits in SGOT and SGPT (Table–13&Figure 13, 14) in high dose treated animals, when compared to control group. In the present study, there was no treatment-related abnormality in renal functions at all the animals (Table -12&Figure-12). The therapeutic dose of Kukkil Chooranam is 2gMS/day for the human uses mentioned in Siddha text. This dose was safest dose in humans for the above studies.

The **histopathological study,** organs such as brain, heart, kidney, liver, lungs, spleen and stomach were taken. In organs of Control group, no abnormality was detected during the study period.

The Literature Review reveals that there was no such research has been done on Kukkil Chooranam. As an initial step, in this present study, a part of standardization of this drug and its safety has been confirmed through necessary analysis and Short term & Long term Toxicity studies as per WHO guidelines.

The clinical study was conducted with a well-defined protocol and a proper proforma after the approval of Institutional Ethical Committee.

For this dissertation study, 40 patients were selected and Patients were treated in the OP/IP department of *SirappuMaruthuvam*, in Ayothidoss Pandithar Hospital - National Institute of Siddha, Tambaram Sanatorium, Chennai –600 047.

Based on various criteria, the data were collected and tabulated. The criteria were family history, sex predominance, age distribution, occupation, dietary habits and incidence of the disease with reference to thinai, seasonal variation, clinical manifestations and assessment of the improvement in the prognosis of the disease with the trial drug.

In Siddha System, it is necessary to bring the vitiated humours to equilibrium. Hence before the treatment *Agathiyar kuzhambu* with *sangankuppi* (*Clerodenruminerme*) juice was given for *Viresanam* (Purgation) in the early morning to normalize the vitiated humours.During the treatment, the patients were advised to follow *pathiyam* (Dietary regimen).

Internal Drug **:** *Kukkil chooranam*- 1gm two times per day with honey.

External Drug **:** *Thuvara ennai* for external application.

Duration of Drug : 48 days

40 patients of both genders were recruited for this study. Among the 40 patients, 33 (82.5%) patients were males and 7(17.5%) patients were females. Generally *Naalavibathapun* Occurs with almost equal frequency in males and females, evidencing the losses that this disease causes in work production. But a slightly higher prevalence noticed in males. In this study, more number of Male cases were reported.

Among 40 patients, 7 (17.5%) patients between 20 and 30 years, 9 (22.5%) patients between 31 and 40 years, 14 (35%) patients between 41 and 50 years, 10 (25%) patients between 51 and 60 years. *Naalavibatha pun*commonly appear at old age than younger. In this present study, considerable numbers of patients were reported (14 patients) between the age of 41-50 among study sample.

The majority of patients in this study were Supervisors 9 (22.5%), Administration Work 8 (20%) and Home Maker 5 (12.5%).

The majority of patients in this study were Non vegetarian 38 (95%) remaining 2 (5%) patients were vegetarian.

In this present study, considerable numbers of patients were reported from *Neithal*(31 patients),*Marutham*(7 patients)*Kurinji (2* patients)*thinai*.

Highest number of patients 30(75%) were admitted during *PinpaniKaalam* (*Maasi&Panguni*) and 10 patients (25%) were admitted during *IllavenilKaalam* (*Chithirai & Vaigasi*).

Most of patients 24 (60%) were affected in durations of above 1 year, 4 (10%) patients were affected by the illness from 10 to 12 months, 3 (7.5%) patients were affected by the illness from 4 to 6 months and 9 (22.5%) patients were affected by the illness from 0 to 3 months.

Out of 40 (100%) patients 40 patients had clinical features of Ulcer, Pain, Hyperpigmentation, Fibrinous exudate and Inflammation, 34 (85%) patients had itching, 35 (87.5%) patients had leg swelling, 32 (80%) patients had eczema around the ulcer.

Laboratory investigations were done for all the cases before and after treatment. There were no variations in hepatic, renal and other parameters.

The outcome of this study was clinically observed by VCSS Score, which showed encouraging results of good improvement in 25 patients (62.5%), moderate improvement in 8 patients (20%), and mild improvement in 7 Patients(17.5%).

In this study, no adverse events were observed during the course of the treatment. At the time of discharge, all the patients were advised to attend Out-Patient Department of Sirappu Maruthuvam of NIS for further follow-up treatment.

SUMMARY

SUMMARY

The disease Naalavibatha pun was taken for the clinical study with *KukkilChooranam* as internal medicine and *Thuvaraennai* as external application. For the clinical study, 40 cases were selected based on the approved protocol.

This study has been approved by **IEC of NIS[Date of IEC Approval& its number: NIS/IEC/9-2014-15/14-26.08.2015].** Animal studies were carried out after obtaining approval from the Institutional Animal Ethical Committee (IAEC) and the trial was registered in Clinical Trial Registry of India (CTRI/2017/05/008584). Hence the study is safely executed on patients and there was no adverse drug reactions noted during the study period.

The toxicological evaluations were conducted as per WHO guidelines for safety evaluation of Kukkil Chooranam. In long term toxicity study, no signs of toxicity and mortality were observed throughout the study period up to the dose of 2000mg/kg body weight. Thus, the LD_{50} value of Kukkil Chooranam was found to be greater than 2000mg/kg body weight.

In Long term toxicity study, there were no significant changes in behavioral signs, food intake, water intake, Lipid Profile, Renal parameters hematological parameters, and Hepatic parameters. The liver function test conducted at the end of the study, test groups (Low, Mid, High dose) revealed no significant changes in level of liver parameters, when compared with control group animals.

In organs of Control group, no abnormality was detected. The normal histological structure present in test group of animals.

Out of the 40 cases, 10 cases were treated in IPD and remaining 30 cases were treated in OPD of Ayothidoss Pandithar Hospital of National Institute of Siddha, Chennai-47. The detailed study on *Naalavibatha pun* with reference to its aetiology, pathogenesis, investigations, clinical features, diagnosis and treatment with trial drugs were done.

The results were observed by VCSS score. Among the 40 cases treated, 62.5% cases had shown Good improvement, 20% cases had shown Moderate improvement and 17.5% had shown Mild improvement.

CONCLUSION

CONCLUSION

The present clinical study confirms the efficacy of the trial drugs *Kukkil chooranam*(Internally) and *Thuvara Ennai(Externally)*. It was found to be good resulting on *Naalavibatha pun* patients in reducing clinical symptoms like ulcer, itching, oozing, pain and oedema.

The Short term and Long term toxicitystudiesdid not show any toxic effects in the animal.

The quantitative outcome of VCSS score shows there is significant reduction between before and after treatment. The qualitative outcome shows there is 62.5% of cases had shown good improvement, 20% of cases had shown moderate improvement and remaining 17.5% of cases had shown mild improvement.

The clinical trial conducted in selected patients was satisfactory and the results were encouraging. However a study with large number of patients is required to fine out the ideal dose response.

The cost of the trail medicines are Low. These drugs are easily available and the dosage is also convenient.

These drugs may be taken up for further exploratory randomised clinical trials to confirm the efficacy.

ANNEXURE

ANNEXURE

The following certificate are enclosed

- Research Methodology Certificate
- IEC Certificate
- IAEC Certificate
- Authentication Certificate

CERTIFICATES

The Tamil Nadu Dr.M.G.R.Medical University

69,Anna Salai,Guindy,Chennai - 600 032.

This Certificate is awarded to Dr/Mr/Mrs.....C.. Sasikala.....

for participating as ~~Resource Person~~ / Delegate in the Nineteenth Workshop on

" RESEARCH METHODOLOGY & BIOSTATISTICS "

*For **AYUSH Post Graduates & Researchers***

Organized by the Department of Siddha

The Tamil Nadu Dr. M.G.R. Medical University from 07 th to 11 th September 2015.

Dr.N.KABILAN, M.D.(Siddha)
READER,DEPT.OF SIDDHA

Prof. **Dr.P.ARUMUGAM,** M.D.,
REGISTRAR I/C

Prof. **Dr.D.SHANTHARAM,** M.D., D.Diab.,
VICE CHANCELLOR

NATIONAL INSTITUTE OF SIDDHA
राष्ट्रीय सिद्ध संस्थान
Department of AYUSH- MINISTRY OF HEALTH & FAMILY WELFARE
आयुष विभाग - स्वास्थ एवं परिवार कल्याण मंत्रालय
GOVERNMENT OF INDIA-भारत सरकार
TAMBARAM SANATORIUM, CHENNAI -600 047 -ताम्बरम सनटोरियम् चेन्नई -600 047
फ़ोन\Tele : 044-22411611 फैक्स\Fax : 22381314
ईमेल: nischennaisiddha@yahoo.co.in वेब :www.nischennai.org

F.No.NIS/6-20/IEC/15-16 Dt: 05.10.2015

CERTIFICATE

Address of Ethics Committee: National Institute of Siddha, Tambaram Sanatorium, Chennai-600047, Tamil Nadu, India	
Principal Investigator: Dr.C.Sasikala, Department of Sirappu Maruthuvam	
Protocol title: "Preclinical and clinical study of Siddha drug Kukkil Chooranam (Internal medicine) and Thuvara Ennai (External medicine) in the treatment of Pun(Naalavibaatha pun-Varicose ulcer)	
Documents filed	1) Protocol, 2) Data Collection forms 3) SAE(Pharmacovigilance)
Clinical trial Protocol (others – Specify)	Yes
Informed consent documents	Yes
Any other documents	-
Date of IEC approval & its number	NIS/IEC/9/2014-15/14 – 26.08.2015

We approve the trial to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study.

Chairman

Member Secretary

CERTIFICATE

This is certify that the project title....Pre clinical and Clinical Study of Siddha drug "kukkil Chooranam(KC)"..... hasbeen approved by the IAEC. 100 Rats (50M + 50f). Approval No. NIS/IAEC-III/06/29092016.

Prof. Dr. V. Banumathi
Name of Chairman/~~Member Secretary~~ IAEC:

Prof. Dr. K. Nachimuthu.
Name of CPCSEA nominee:

Signature with date

V. Banumathi

Chairman/~~Member Secretary~~ of IAEC:

29/4/2016

CPCSEA nominee:

(Kindly make sure that minutes of the meeting duly signed by all the participants are maintained by Office)

Name of the principal investigator - Dr. C. Sasikala

Name of the Department - Sirappu Maruthuvam

NATIONAL INSTITUTE OF SIDDHA, CHENNAI – 600047

BOTANICAL CERTIFICATE

Certified that the following plant drugs used in the Siddha formulation **"Kukkil chooranam"** (Internal) and **Thuvara Ennai** (External) for taken up for Post Graduation Dissertation studies by **Dr.C.Sasikala**, M.D.(S), II year, Department of Sirappu Maruthuvam, 2016, are identified through Visual inspection, Experience, Education & Training, Organoleptic characters, Morphology and Taxonomical methods as

Smilax china Linn. (Liliaceae), Root
Shorea robusta Gaertn f. (Dipterocarpaceae), Oleoresin
Piper nigrum Linn. (Piperaceae), Fruit
Piper longum Linn. (Piperaceae), Fruit
Hyoscyamus niger Linn. (Solanaceae), Fruit
Myristica fragrans Houtt. (Myristicaceae), Aril
Myristica fragrans Houtt. (Myristicaceae), Nut
Terminalia belerica Roxb. (Combretaceae), Fruit
Alpinia officinarum Hance (Zingiberaceae), Rhizome
Cuminum cyminum Linn. (Apiaceae), Fruit
Phyllanthus emblica Linn. (Euphorbiaceae), Fruit
Acacia catechu Wild. (Mimosaceae), Wood extract
Areca catechu Linn. (Arecaceae), Nut
Terminalia chebula Retz. (Combretaceae), Fruit
Terminalia chebula Retz. (Combretaceae), Gall
Ventilago madraspatana Gaertn. (Rhamnaceae), Root bark
Santalum album Linn. (Santalaceae), Heart wood powder

MEDICINAL BOTANY ★ CHENNAI 600 047 ★ National Institute of Siddha

Certificate No: NISMB2582016

Date: 11-11-2016

11/11/16

Authorized Signatory
Dr. D. ARAVIND, M.D.(s),M.Sc.,
Assistant Professor
Department of Medicinal Botany
National Institute of Siddha
Chennai - 600 047. INDIA

சித்த மருத்துவ மைய ஆராய்ச்சி நிலையம், சென்னை - **600 106**
सिद्ध केंद्रीय अनुसन्धान संस्थान,
अण्णा सरकारी अस्पताल परिसर, अरुम्बाक्कम, चेन्नई – 600 106
SIDDHA CENTRAL RESEARCH INSTITUTE
(Central Council for Research in Siddha, Ministry of AYUSH, Govt. of India)
Anna Govt. Hospital Campus, Arumbakkam, Chennai – 600106
Phone: 044-2621 4925, Fax: 044-2621 4809
Website : www.siddhacouncil.com / Email : crisiddha@gmail.com

24.05.2016

CERTIFICATE

Certified that the samples submitted for identification by Dr. C. Sasikala, II Year MD Student, Department of Sirappu Maruthuvam, National Institute of Siddha, Chennai-600 047 are identified as Gandhagam – Sulphur and Thurusu – Copper sulphate.

(R. Shakila)
Research Officer (Chemistry) & Head,
Department of Chemistry

(Dr. P. Elankani)
Research Officer (Scientist II) (Siddha)
for Assistant Director (Siddha) I/c

CASE SHEET PROFORMA

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL, **CHENNAI – 600 047.**

POST - GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

Preclinical and clinical study of siddha drug ***"kukkil chooranam"*** (internal) and **"*thuvara ennai"*** (external) in the treatment of ***pun*** (*naalavibatha viranam*-varicose ulcer).

FORM l - SCREENING & SELECTION PROFORMA

SL.NO **OP NO:**

NAME: **AGE/GENDER:** **CONTACT NO:**

INCLUSION CRITERIA

Age :20-60Yrs	Yes/ No	Fibrunous exudate	Yes/ No
Sex	M/F	Skin pigmentation	Yes/ No
Ulcer with varicose vein	Yes/ No	Inflammation	Yes/ No
Pain	Yes/ No	Induration	Yes/No
Edema	Yes/ No	Itching	Yes/No
Eczema around ulcer	Yes/ No	Permit to take photograph	Yes/ No
Willing to give blood for investigation	Yes/ No	Willing to participate in trial and signing consent by fulfilling the condition of Performa.	Yes/ No

If the symptom more than 3, may be included for the clinical trial.

EXCLUSION CRITERIA: H/O

Diabetes mellitus	Yes/No	Gangrene	Yes/ No
Tuberculous ulcer	Yes/No	Hanson's disease	Yes/No
Diabetic ulcer	Yes/No	Any other systemic illness	Yes/No

ADMITED TO TRIAL: YES ☐ NOIf yes, ☐ No: ☐☐

OPD IPD ☐ ☐

Date:

Station: Signature of the Lecturer:

Signature of the Investigator: Signature of the HOD

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSS PANDITHAR HOSPITAL

CHENNAI – 600 047.

POST - GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUG ***"KUKKIL CHOORANAM"*** (INTERNAL) AND ***"THUVARA ENNAI"*** (EXTERNAL) IN THE TREATMENT OF ***PUN*** (*NAALAVIBATHA PUN*-VARICOSE ULCER).

[PRINCIPAL INVESTIGATOR]

FORM II – HISTORY TAKING FORM

STUDY NO **OP / IP NO:**

NAME: **AGE/GENDER:**

ADDRESS: **CONTACT NO:**

RELIGION: H / M / C / O

OCCUPATION: **INCOME:**

MARRITAL STATUS: MARRIED ☐ **UNMARRIED** ☐

DATE OF INITIAL ASSESSMENT:

COMPLAINTS & DURATION:

PERSONAL HISTORY:

PERSONAL HABITS	YES	NO	IF YES SPECIFY DURATION	AMOUNT/Qty
Smoking				
Tobacco Chewing				
Alcohol				
Narcotic Drug Addiction				

HISTORY OF PREVIOUS ILLNESS AND TREATMENT TAKEN:

FAMILY HISTORY:

Whether this problem runs in family? 1. Yes ☐ 2.No ☐

If yes, mention the relationship of affected person(s)

1._____ 2._____

DIETARY HABIT: 1.Vegetarian ☐ 2.Non-vegetarian ☐

MENSTURAL HISTORY AND OBSTETRIC HISTORY:

FORM II a

GENERAL EXAMINATION:

1. Body weight [Kg] :
2. Height [cms] :
3. Body Temperature [^{0}F] :
4. Blood Pressure (mm/Hg) :
5. Pulse Rate /min. :
6. Heart Rate / min. :
7. Respiratory Rate /min. :

		Yes	**No**
8.	Pallor :	☐	☐
9.	Jaundice :	☐	☐
10.	Clubbing :	☐	☐
11.	Cyanosis :	☐	☐
12.	Pedal Oedema :	☐	☐
13.	Lymphadenopathy :	☐	☐
14.	Jugular venous pulsation :	☐	☐

VITAL ORGANS EXAMINATION:	**Normal**	**Abnormal**
1. Heart	☐	☐
2. Lungs	☐	☐
3. Brain	☐	☐
4. Liver	☐	☐
5. Kidney	☐	☐
6. Spleen	☐	☐
7. Stomach	☐	☐

SYSTEMIC EXAMINATION:	**Normal**	**Abnormal**
1. Cardio-vascular system	☐	☐
2. Respiratory system	☐	☐
3. Gastro intestinal system	☐	☐
4. Central nervous system	☐	☐
5. Uro-genital system	☐	☐
6. Endocrine system	☐	☐

SIDDHA SYSTEM OF EXAMINATION

1. THEGI (TYPE OF BODY CONSTITUTION):

1. Vaatha udal ☐ 3. Kaba udal ☐

2. Pitha udal ☐ 4. Thontha udal ☐

2. NILAM (LAND WHERE THE PATIENT LIVED MOST):

1. Kurinji ☐ 3. Paalai ☐

2. Mullai ☐ 4. Neithal ☐

5. Marutham ☐

3. KAALAM:

1. Kaar kaalam ☐ 4. Pinpani kaalam ☐

2. Koothir kaalam ☐ 5. Ilavenil kaalam ☐

3. Munpani kaalam ☐ 6. Muthuvenil kaalam ☐

4. GUNAM:

1. Sathuvam ☐ 2. Rasogunam ☐

3. Thamogunam ☐

5. PORIPULANGAL (SENSORY ORGANS):

	Before treatment	**After treatment**
Mei (Skin)	Normal / Affected	Normal / Affected
Vai (Tongue)	Normal / Affected	Normal / Affected
Kann (Eye)	Normal / Affected	Normal / Affected
Mooku (Nose)	Normal / Affected	Normal / Affected
Sevi (Ear)	Normal / Affected	Normal / Affected

6.KANMENDRIYAM (MOTOR ORGANS) :

	Before treatment	**After treatment**
Kai	Normal /Affected	Normal /Affected
Kaal	Normal /Affected	Normal /Affected
Vai	Normal /Affected	Normal /Affected
Eruvai	Normal /Affected	Normal /Affected
Karuvai	Normal /Affected	Normal /Affected

7. KOSANGAL (SHEATH):

	Before treatment	**After treatment**
Annamayakosam	Normal /Affected	Normal /Affected
Pranamayakosam	Normal /Affected	Normal /Affected

Manomayakosam	Normal /Affected	Normal /Affected
Vignanamayakosam	Normal /Affected	Normal /Affected
Ananthamayakosam	Normal /Affected	Normal /Affected

8.SEVEN UDAL THAATHUKKAL (SEVEN SOMATIC COMPONENTS)

	Before treatment	**After treatment**
Saaram	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected
Moolai	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected

8.UYIR THATHUKKAL (THREE HUMOURS):

A. VALI

	1st day	8thday	15th day	22nd day	29thday	36th day	43rd day	49th day
Praanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Abaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Viyaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Udhaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Samaanan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Naagan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Koorman	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kirukaran	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Devathathan	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Dhananjeya	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

B) AZHAL

	1st day	**8th Day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**
Analakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Prasakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Ranjakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Aalosakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Saathakam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

C. IYAM:

	1st day	**8th day**	**15thday**	**22nd day**	**29thday**	**36thday**	**43rdday**	**49th day**
Avalambagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kilethagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Pothagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Tharpagam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Santhigam	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

9.SEVEN UDAL DHATHUS: (7 SOMATIC COMPONENTS)

	1st day	**8thday**	**15thday**	**22nd day**	**29thday**	**36th day**	**43rdday**	**49th day**
Saaram	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Senneer	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Oon	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Kozhuppu	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Enbu	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

Moolai	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected
Sukkilam / Suronitham	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected	Normal /Affected

ENVAGAI THERVU: [EIGHT TYPES OF EXAMINATION]

I. NAADI: [PULSE PERCEPTION]

1st Day	**8th day**	**15th day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**

II. SPARISAM:

1st Day	**8th Day**	**15th Day**	**22nd day**	**29th day**	**36th day**	**43rd day**	**49th day**

III. NAA:[TONGUE]

1st Day	**8th Day**	**15th Day**	**22nd Day**	**29th Day**	**36th Day**	**43rd Day**	**49th Day**

VI.NIRAM: [COMPLEXION]

1. Vaatham ☐ 3. Kabam ☐

2. Pitham ☐

V.MOZHI: [VOICE]

1. High Pitched ☐ 2. Low Pitched ☐

3. Medium Pitched ☐

VI.VIZHI: [EYES]

1st Day	**8th Day**	**15th Day**	**22nd Day**	**29th Day**	**36th Day**	**43rd Day**	**49th Day**

VII. MALAM: [BOWEL HABITS / STOOLS]

	Before treatment	**After treatment**
Niram		
Irugal		
Ilagal		
Others		

VIII. MOOTHIRAM [URINE EXAMINATION]

Neerkkuri	**Before treatment**	**After treatment**
Niram		
Manam		
Edai		
Nurai		
Enjal		

NEIKURI	**Before treatment**	**After treatment**
Aravu (Serpentine fashion)		
Aazhi (Annular/Ringed fashion)		
Muthu (Pearl beaded fashion)		
Kalappu (Mixed fashion)		
Other fashion		

CLINICAL EXAMINATION:
CLINICAL EXAMINATION OF WOUND:

1.Site: ----------

2.Duration:----------

3. Size:

	1st Day	**8th Day**	**15th Day**	**22th Day**	**29th Day**	**36th Day**	**43rd Day**	**49th Day**
Length								
Width								
Depth								

4. Shape: Irregular ☐ Oval ☐ Semi lunar ☐

5. Nature of Edges: Undetermined ☐ Sloping edges ☐ Everted ☐

Punched out ☐ Raised ☐

6.Character of the Floor: Pale granulation tissue ☐ Black mass ☐

Red granulation tissue ☐ Wash leather slough ☐

7.Discharge: Present ☐ Absent ☐

8.Associated pain: Present Absent ☐ ☐

9.Surrounding skin: Hyperpigmented Hypopigmented ☐

Erythematous ☐

10. Lymph node enlargement: Present ☐ ☐

FORM II B-CLINICAL ASSESSMENT DURING AND AFTER TRIAL

OP/ IP NO: **STUDY NO:** **NAME:**

AGE/GENDER: **DATE OF RECRUITMENT:**

VENOUS CLINICAL SEVERITY SCORE

ATTRIBUTE	ABSENT=0	MILD=1	MODERATE=2	SEVERE=3
PAIN	None	Occasional, not Restricting activity or requiring pain Medication	Daily moderate activity imitation; occasional Pain medication	Daily, severe limiting Activities or requiring Regular use of pain Medications
VARICOSE VEINS	None	Few scattered	Multiple; great Saphenousveins, confined to calf And thigh	Extensive; thigh and calf or Great and small saphenous Distribution
VENOUS EDEMA	None	Evening ankle swelling Only	Afternoon Swelling, Above ankle	Morning swelling above Ankle and requiring Activity change, elevation
SKIN PIGMENTATIO N	None	Diffuse, but limited in Area and old (brown)	Diffuse over most ofgaiter distribution(lowerthird) or recent Pigmentation (purple)	Wider distribution (above Lower third) plus recent Pigmentation
INFLAMMATIO N	None	Mild cellulitis, limited To marginal area Around ulcer	Moderate cellulitis, Involves most of (lower third)	Severe cellulitis (lower Third and above) Or significant
INDURATION	None	Focal, circummalleol ar	Medial or lateral, lessthan lower third of leg	Entire lower third of leg or more
NUMBER OF ACTIVE ULCERS	0	1	2	>2
ACTIVE ULCER DURATION	None	<3 months	>3 months, <1year	Not healed>1 year
ACTIVE ULCER DIAMETER	None	<2	2-6	>6
COMPRESSION THERAPY	Not used or Patient not Compliant	Intermittant use of Stockings	Wears elastic stocking Most days	Full compliance, Stockings+elevation

	1st Day	8th Day	15th Day	22th Day	29th Day	36th Day	43rd Day	49th Day
Vcss score								

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

NATIONAL INSTITUTE OF SIDDHA

AYOTHIDOSSPANDITHARHOSPITAL

CHENNAI – 600 047.

POST-GRADUATE DEPARTMENT OF SIRAPPU MARUTHUVAM

PRECLINICAL AND CLINICAL STUDY OF SIDDHA DRUG ***"KUKKIL CHOORANAM"*** (INTERNAL) AND ***"THUVARA ENNAI"*** (EXTERNAL) IN THE TREATMENT OF ***PUN (****NAALAVIBATHA VIRANAM*-VARICOSE ULCER).

[PRINCIPAL INVESTIGATOR]

FORM-III – LABORATORY INVESTIGATIONS PROFORMA

STUDY NO: OP / IP NO: AGE/GENDER:

BLOOD INVESTIGATIONS		**NORMAL VALUES**	**BEFORE TMT (DATE)**	**AFTER TMT (DATE)**
Hb(gm/dl)		**M:12-15 F:11.5-14**		
T.WBC (cells/cu.mm)		**4000-11000**		
DIFFERENTIAL COUNT (%)	**Polymorphs**	**40-75**		
	Lymphocytes	**20-40**		
	Monocytes	**2-10**		
	Eosinophils	**1-6**		
	Basophils	**0-1**		
T.RBC(million cells/cu.mm)		**M:4.0-5.5 F:3.5-4.5**		
ESR(mm/hour)	**½ hr.**	**M:1-13 F:1-20**		
	1 hr.			

Blood Investigations		Normal Values	Before TMT (DATE)	After TMT (DATE)
Blood glucose (mg/dl)	Fasting	70-110		
	PP	80-140		
	Random	80-120		
RFT (mg/dl)	Blood urea	16-50		
	Serum creatinine	0.6-1.2		
	Serum uric acid	M:3-9 F:2.5-7.5		
LFT (mg/dl)	Total bilirubin	0.2-1.2		
	Direct bilirubin	0.1-1.2		
	Indirect bilirubin	0.2-0.7		
	SGOT (IU/L)	0-40		
	SGPT (IU/L)	0-35		
	Alkaline phosphatase(IU/L)	80-290		

Urine investigations	Before TMT(Date)	After TMT (Date)
Albumin		
Fasting sugar		
PP sugar		
Deposits		

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

FORM V – PATIENT INFORMATION SHEET

Name of Principal Investigator: Dr.C.Sasikala

Name of the institute: National Institute of Siddha,

Tambaram Sanatorium, Chennai-47.

I, Dr.C.Sasikala studying M.D(Siddha) at National Institute of Siddha, Tambaram Sanatorium is doing a trial on *PUN* (*Naalavibatha Pun*-Varicose ulcer).Varicose ulcer is a most common persistent skin disease, occurring throughout the world. In this regard, I am in a need to ask you few questions. I will maintain confidentiality of your comments and data obtained. There will be no risk of disclosing your identity and no physical, psychological or professional risk is involved by taking part in this study. Taking part in this study is voluntary. No compensation will be paid to you for taking part in this study.

You can choose not to take part. You can choose not to answer a specific question. There is no specific benefit for you if you take part in the study. However, taking part in the study may be of benefit to the community, as it may help us to understand the problem of defaulters and potential solutions.

If you agree to be a participant in this study, you will be included in the study primarily by signing the consent form and then you will be given the internal medicine *KUKKIL CHOORANAM* (Internal medicine-1g BD for 48 days) and*THUVARA ENNAI*(External medicine), if you wish to stay in the In-Patient ward Treatment will be provided to you assuring that you will not be definitely hurt in any course of treatment.

The information I am collecting in this study will remain confidential. I will ask you few questions through a questionnaire. It will take approximately 20 min of time. Your name won't be mentioned in the lab investigation form instead a code will be used.

If you wish to find out more about this study before taking part, you can ask me all the questions you want or contact Dr.C.Sasikala, PG Scholar cum principal investigator of this study, National Institute of Siddha, Chennai-47. You can also contact the Member-secretary of Ethics committee, National Institute of Siddha, Chennai 600047, and Tel No: 044-22380789 for rights and participation in the study.

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாஸ் பண்டிதர் மருத்துவமனை - சென்னை 47

புண் (நாளவிபாத புண்)நோய்க்கான சித்த மருந்துகளின் (குக்கில் சூரணம் மற்றும்துவர எண்ணெய்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கான தகவல் படிவம்.

முதன்மை ஆராய்ச்சியாளர் பெயர்: மருத்துவர் : சி.சசிகலா

நிறுவனத்தின் பெயர் : தேசிய சித்த மருத்துவ நிறுவனம்

தேசிய சித்த மருத்துவ நிறுவனத்தில் பட்ட மேற்படிப்பு பயின்று வரும் நான் மருத்துவர் சி.சசிகலா நாளவிபாத புண் என்னும் நோயில்மருத்துவ ஆராய்ச்சியில் ஈடுபட்டுள்ளேன்.புண்என்னும் நோய் உண்டாவதற்கான அடிப்படை காரணம் கிருமிகள் அன்று. கட்டி உடைவதனாலும், கருவியினாலும், அடிபடுவதாலும், நெருப்பினாலும், பிற உயிர்களின் கடிகளாலும் உண்டாவதாக கூறப்படுகிறது. - து பரவ கூடிய நோய் அன்று. - ந்த ஆராய்ச்சி சம்பந்தமாக சில கேள்விகளை கேட்கவும், தேவையான ஆய்வக பரிசோதனைக்கு தங்களை உட்படுத்தவும் உள்ளேன்.- து சம்பந்தமான தங்களது அனைத்து விவரங்களும் ரகசியமாக வைக்கப்படும் என உறுதி அளிக்கிறேன். - தில் பயணப்படி முதலிய எந்த உதவித் தொகையும் வழங்கப்பட மாட்டாது. - ந்த ஆராய்ச்சியின் போது உடலுக்கு வேறு பாதிப்பு ஏற்படும் பட்சத்தில் தேசிய சித்த மருத்துவமனையில் தக்க சிகிச்சை அளிக்கப்படும்.- ந்த ஆராய்ச்சிக்கு தங்கள் விருப்பத்தின் பேரில் உட்படும் பட்சத்தில் உள்மருந்தாக குக்கில் சூரணம், தேன் (1gm) 2வேளை (காலை,மாலை) உணவுக்குப் பின் 48 நாட்கள் உட்கொள்ள வேண்டும். வெளி மருந்தாக துவர எண்ணெய்வெளியே தடவ வேண்டும். வெளி நோயாளர்கள் 7 நாட்களுக்கு ஒருமுறை மருத்துவமனைக்கு வரவேண்டும். உள் நோயாளியாக தங்க விருப்பம் தெரிவிக்கும் பட்சத்தில் நோய்க்கு தகுந்த சிகிச்சை அளிக்கப்படும். - ந்த ஆராய்ச்சியில் நோயினராக சேர்ந்த பிறகு உங்களுக்கு விருப்பம் - ல்லையெனில் எப்போது வேண்டுமானாலும் விலகி கொள்ளலாம். - ந்த ஆராய்ச்சி சம்பந்தமாக மற்ற விபரங்களுக்கும் நோயின் தன்மை பற்றியும் முதன்மை ஆராய்ச்சியாளரான மருத்துவர்: சி.சசிகலா (பட்ட மேற் படிப்பாளர் சிறப்பு மருத்துவ துறை) அணுகவும். கைப்பேசி எண் 9787581114. மேலும் - ந்த ஆராய்ச்சிக்கு IEC சான்று பெறப்பட்டுள்ளது. - ந்த மருந்து சிறப்பாகபுண் நோய்க்காக அங்கீகரிக்கப்பட்ட சித்த மருத்துவ நூலில் கூறப்பட்டுள்ளது. ஏற்கனவே உபயோகத்தில் உள்ள - து போன்ற மருந்து - துவரை நோயாளிகளிடம் எந்த விதபக்க விளைவுகளையும் ஏற்படுத்தவில்லை. மேலும் உணவு முறையில் மருத்துவரால் கூறப்படும் பத்தியம் காக்குமாறு அறிவுறுத்தப்படுகிறது.

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FORM VI: INFORMED CONSENT FORM

"I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction.

I consent voluntarily to participate in this study and understand that I have the right to withdraw from the study at any time without affecting my further medical care".

"I have received a copy of the information sheet/consent form".

Signature of the participant:

In case of illiterate participant

"I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely."

Date:

Signature of a witness Left thumb Impression

Of the Participant

(Selected by the participant bearing no connection with the survey team)

Signature of the Investigator

Signature of the Lecturer **Signature of the HOD**

தேசிய சித்த மருத்துவ நிறுவனம்

அயோத்திதாஸ் பண்டிதர் மருத்துவமனை-சென்னை 47

புண் (நாளவிபாத புண்) நோய்க்கான சித்த மருந்துகளின் (குக்கில் சூரணம் மற்றும்துவர எண்ணெய்) பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கானஒப்புதல் படிவம்-ஆய்வாளரால் சான்றளிக்கப்பட்டது

நான் - ந்த ஆய்வு குறித்த அனைத்து விபரங்களையும் நோயாளிக்கு புரியும் வகையில் எடுத்துரைத்தேன் என உறுதியளிக்கிறேன்.

தேதி: **கையொப்பம்:**

- டம்: **பெயர்** :

நோயாளியின் ஒப்புதல்

என்னிடம் - ந்த மருத்துவ ஆய்வின் காரணத்தையும், மருந்தின் தன்மை மற்றும் மருத்துவ வழிமுறை பற்றியும், தொடர்ந்து எனது உடல் - யக்கத்தை கண்காணிக்கவும், அதனை பாதுகாக்கவும் பயன்படும் மருத்துவ ஆய்வுக்கூட பரிசோதனைகள் பற்றி திருப்தி அளிக்கும் வகையில் ஆய்வு மருத்துவரால் விளக்கிக் கூறப்பட்டது.

நான் - ந்த மருத்துவ ஆய்வின் போது, எப்பொழுது வேண்டுமானாலும் - ந்த ஆய்விலிருந்து என்னை விடுவித்து கொள்ளும் உரிமையை தெரிந்திருக்கின்றேன். நான் என்னுடைய சுதந்திரமாக தேர்வு செய்யும் உரிமையைக் கொண்டு புண் (நாளவிபாத புண்)நோய்க்கானகுக்கில் சூரணம் (உள் மருந்து)மற்றும்துவர எண்ணெய் (வெளி மருந்து) மருந்தின் பரிகரிப்புத் திறனைக் கண்டறியும் மருத்துவ ஆய்விற்கு என்னை உட்படுத்த ஒப்புதல் அளிக்கிறேன்.

தேதி: **கையொப்பம்:**

- டம்: **பெயர் :**

உறவுமுறை: **சாட்சிக்காரர் கையொப்பம்:**

பெயர்:

விரிவுரையாளர் கையொப்பம்: **துறைத்தலைவர் கையொப்பம்**

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Name of Principal Investigator: Dr.C.SASIKALA

FORM VII -WITHDRAWAL FORM

1. SERIAL NO OF THE CASE:

2. OP / IP NO:

3. NAME:

4. AGE:

5. GENDER:

6. DATE OF TRIAL COMMENCEMENT:

7. DATE OF WITHDRAWAL FROM TRIAL:

8. REASONS FOR WITHDRAWAL:

Long absence at reporting:	Yes/ No
Irregular treatment:	Yes/ No
Shift of locality:	Yes/No
Increase in severity of symptoms:	Yes/No
Development of severe adverse drug reactions:	Yes/No
Development of adverse event:	Yes/No

(If YES, give the details of adverse reaction in Form VII -B – Adverse Reaction Form / Pharmaco Vigilance Form)

Date:

Station:

Signature of the Investigator:

Signature of the Lecturer: **Signature of the HOD**

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Name of Principal Investigator: Dr.C.Sasikala

FORM VIII – DIETARY ADVICE FORM

சேர்க்க கூடிய உணவுகள்	தவிர்க்க வேண்டியவைகள்
முருங்கைப்பிஞ்சு	கோழிக்கறி
அவரைப்பிஞ்சு	மீன்
காரட்	நண்டு
பீட்ரூட்	கருவாடு
கரிசாலை	முட்டை
பொன்னாங்கண்ணி	பால்
மணத்தக்காளி	பால் பொருள்கள்
முருங்கைக்கீரை	புளிப்புப் பொருள்கள்
பசலைக்கீரை	வேர்க்கடலை
சிறுகீரை	எள்ளு
கறிவேப்பிலை	அன்னாசி
கொத்தமல்லி	நல்லெண்ணெய்
மாதுளை	எலுமிச்சை
ஆப்பிள்	தக்காளி
பேரீச்சை	புளிப்பு தயிர் மோர்
திராட்சை	ஊறுகாய்
கொய்யா	பெண்போகம்
நாவல்	வெற்றிலை,பாக்கு
சப்போட்டா	புகையிலை
உலர் திராட்சை	மது அருந்துதல்
வேகவைத்த காய்கறிகள்	

BIBLIOGRAPHY

BIBLIOGRAPHY

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